UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF LOUISIANA, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, CITY OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, and STATE OF WISCONSIN *ex rel.* SMSPF, LLC, AND PANZEY BELGIUM HARRIS,

Plaintiffs,

v.

EMD SERONO, INC., PFIZER, INC., QUINTILES IMS HOLDINGS, INC., successor by merger to QUINTILES TRANSNATIONAL HOLDINGS, INC., and RXC ACQUISITION COMPANY d/b/a RXCROSSROADS,

Defendants.

Civil Action No: 2:16-cv-05594-TJS

SECOND AMENDED COMPLAINT AND JURY DEMAND

The United States of America (the "United States") and the Plaintiff States (the United States and Plaintiff States are collectively referred to herein as the "Government"), by and through their qui tam Relators SMSPF, LLC and Panzey Belgium Harris (the "Relator"), allege:

PRELIMINARY STATEMENT

1. This is a civil action brought on behalf of the United States of America, ex rel. SMSPF, LLC, by and through their Relators SMSPF, LLC and Panzey Belgium Harris, ("Plaintiffs") against EMD Serono, Inc. ("Serono") and Pfizer, Inc. ("Pfizer," and together with Serono, the "Drug Companies"), and Quintiles IMS Holdings, Inc.,[1] ("Quintiles") successor by merger to Quintiles Transnational Holdings, Inc., and RXC Acquisition Company d/b/a RxCrossroads ("RXC," and together with Quintiles, the "Consultants") under the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "False Claims Act" or "FCA"), and the false claims acts of the respective Plaintiff States[2] to recover treble damages sustained by (and civil penalties and

[1] Since the initial filing of this action in 2016, Defendant Quintiles IMS Holdings merged and is currently known as "IQVIA, Inc."

[2] The state statues are the: (1) California False Claims Act, Cal. Gov't Code §§ 12650- 12656; (2) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5-4-310; (3) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274-289; (4) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201-1211; (5) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01-381.10; (6) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081-68.092; (7) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168-4-168.6; (8) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21-31; (9) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1-175/8; (10) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1-5.5- 18; (11) Iowa False Claims Act, Iowa Code Ann. §§ 685.1-685.7; (12) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1-440.16; (13) Maryland False Claims Act, Md. Code Ann. Health-Gen. §§ 8-101-111; (14) Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A-5O; (15) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601-400.615; (16) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01- 15C.16; (17) Montana False Claims Act, Mont. Code Ann. §§ 17-8-401-416; (18) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010- 357.250; (19) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1-32C-18; (20) New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1-14-15; (21) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1-9-14; (22) New York False Claims Act, N.Y. Fin. Law §§ 187-194; (23) North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605-618; (24) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053-5054; (25) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1-1.1-9; (26) Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101-108; (27) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181-185; (28) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001-36.132; (29) Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630-642; (30) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-216.1-216.19; and (31) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005-74.66.130.

restitution owed to) the Government as a result of three intertwined, unlawful kickback schemes involving the Drug Companies and the Consultants (collectively, the "Defendants") to enrich themselves through three unlawful schemes to promote and drive the sales of the multiple sclerosis drug, Rebif, at the expense of the state and federal Governments.

2. First, from 2006 to the present, the Drug Companies paid millions of dollars to deploy specialized clinicians (i.e., Nurse Educators) to recommend the Drug Companies' multiple sclerosis ("MS") drug to both Prescribers and patients under the guise of education and counseling – a variation on a scheme the United States Department of Health and Human Services ("HHS") Office of the Inspector General (the "HHS-OIG") refers to disapprovingly as a "White Coat Marketing scheme." While purporting to provide independent medical advice and disease-awareness information, the RXC and Quintiles nurses were in reality sales representatives ("sales rep(s)") for Serono and Pfizer, focused on the mission they were paid to accomplish: promoting and recommending Rebif to Prescribers[3] and patients in an effort to drive Rebif sales.

3. Second, from 2006 to the present, the Drug Companies have paid tens of millions of dollars to the Consultants in a *"Free Nurse Kickback Scheme"* to unlawfully provide reimbursement support services to Prescribers in exchange for a recommendation of the Drug Companies' drug used to treat MS.

4. Third, from 2006 to present, the Drug Companies and Consultants' clinicians engaged in a *"Reimbursement Support Services Kickback Scheme"* providing in-kind remuneration in the form of free reimbursement support services to Prescribers, saving Prescribers thousands of dollars in administrative expenses. These reimbursement support services were provided in part to induce those Prescribers to prescribe Rebif to their patients.

[3] As used herein, the term "Prescriber" refers to any physician or Healthcare Provider authorized to write prescriptions, as well as their employers.

5. In a $200 million deal, Pfizer agreed with Serono to co-promote and sell Rebif in the United States in exchange for a portion of all United States sales of Rebif. Pfizer and Serono then partnered with RXC and Quintiles to design and implement the three unlawful marketing and kickback schemes.

6. As will be detailed herein, Defendants knowingly and intentionally worked together to design and implement the *"White Coat Marketing Scheme,"* the *"Free Nurse Kickback Scheme,"* and the *"Reimbursement Support Services Kickback Scheme"* with the goal of defrauding the Government by causing the submission of claims for Rebif that were knowingly and intentionally induced by unlawful remuneration. Perhaps most alarmingly and detailed herein, the schemes worked together to perniciously exploit the sacred level of trust between physicians, nurses and patients while it was dressed up and papered over so as to not attract suspicion and to thwart official scrutiny.

7. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"), expressly prohibits any individual or entity from offering, paying, soliciting, or receiving any "remuneration," which includes "any kickback, bribe, or rebate," to "any person to induce such person" to purchase or recommend a drug or service that is covered by Medicare or Medicaid. *Id.* Further, the U.S. Department of Health and Human Services (the "HHS") has repeatedly warned pharmaceutical companies that they should refrain from engaging in marketing or promotional activities that utilize individuals who are involved in the delivery of healthcare or rely on the provision of free services such as billing, nursing, or other staff services.[4]

8. The AKS ensures that the Government pays only for conflict-free medical care and prescriptions that are provided in the best interests of the patient. A kickback eliminates any sound

[4] *See, e.g.*, 56 Fed. Reg. 35952-01, 35981 (July 29, 1991); 59 Fed. Reg. 65372-01, 65376 (Dec. 19, 1994).

basis for such assurance because it taints the prescribing physician's medical decisions with the physician's financial interests. "The Government does not get what it bargained for when a defendant is paid by [the Government] for services tainted by a kickback."[5]

9. Despite the clear prohibitions of the law, Defendants designed and implemented these three intertwined, sophisticated schemes to circumvent these bright line legal prohibitions. These schemes by intention and effect undermined and compromised the decision making of Prescribers, an important safeguard and foundational underpinning of federal healthcare program coverage policy and actively exploited patient vulnerabilities. The Prescribers prescribing the Drug Companies' drug did not do so because they believed, based on their review of peer-reviewed medical literature or discussion with their colleagues, that the drugs would be the most efficient means of helping their patients. Rather, the Drug Companies' drug was and is often prescribed to patients because Defendants actively and improperly pursued and enticed Prescribers with kickbacks that would increase Prescribers' profits and reduce administrative burdens for prescribing MS drugs.

10. As a result of Defendants' unlawful marketing schemes, which violate the AKS, pharmacies have and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay millions of dollars in improper reimbursements.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the claims Relators bring on behalf of the United States under the FCA pursuant to 28 U.S.C. §§ 1331 and 1345.

[5] *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011)(internal quotations omitted).

12. This Court may exercise personal jurisdiction over Serono, Pfizer, Quintiles and RXC because a substantial part of the acts giving rise to Plaintiffs' claims occurred within the Commonwealth of Pennsylvania.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) as well as 28 U.S.C. §§ 1391(b) and (c) because the Defendants each transacted and continue to transact business in this District and, in furtherance of its fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District.

PARTIES

14. Defendant EMD Serono, Inc. is a Delaware corporation, headquartered in Rockland, Massachusetts. A subsidiary of Merck KGaA, Serono manufactures interferon beta-1a, a drug for treating MS marketed and sold in the United States as "Rebif."

15. Defendant Pfizer, Inc., is a Delaware corporation, headquartered in Gladstone, New Jersey.

16. Defendant Quintiles, Inc. (successor by merger to Quintiles, Inc. and formerly Quintiles and IMS Health, Inc.) is a Delaware corporation, headquartered in Durham, North Carolina. It is the world's largest provider of biopharmaceutical development services and business services, including, conducting services in over 100 countries and generating over $3.7 billion in revenue in 2012.

17. Defendant RXC Acquisition Company d/b/a RxCrossroads is a Delaware corporation with headquarters in Louisville, Kentucky. Like Quintiles, RXC is a commercial outsourcing company that, according to their website, provides services for pharmaceutical companies to "positively impact[] access and commercial success of their products." RXC was a subsidiary of CVS Health but was sold to McKesson Corporation on December 11, 2017.

18. Relator, SMSPF, LLC, is a Delaware limited liability company.

19. Relator, Panzey Belgium Harris, is an individual who resides in Mableton, Georgia, who worked for Pfizer as a therapeutic account specialist from January 2015 to March 2016. Mr. Harris and other healthcare professionals set forth in the complaint individually and collectively have original source information of many of the facts set forth in this Second Amended Complaint.

20. Relators bring this action on behalf of the Government pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. §§ 3729-3733, and the false claims acts of the respective Plaintiff States.

STATUTORY BACKGROUND

A. The False Claims Act

21. The United States may recover treble damages pursuant to the FCA from any individual or entity that:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> (C) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.
>
> [31 U.S.C. § 3729(a)(1)(A)-(C).]

22. Within the meaning of the FCA, "knowingly" is defined to include reckless disregard and deliberate ignorance. 31 U.S.C. § 3729(b)(1).

23. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim ranging from $5,500 to $11,000. 31 U.S.C. § 3729(1)(G); 64 F.R. 47099, 47104 (1999).

B. The Anti-Kickback Statute

24. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), states as follows, in relevant part:

> (b) Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

25. For purposes of the AKS, "remuneration" includes the transfer of "anything of value," whether cash or in-kind consideration, directly or indirectly, covertly or overtly. Importantly, the statute has been consistently interpreted broadly to cover any arrangement where

the *only* purpose of the remuneration is to obtain money for referral of services or to induce further referrals even if there were other valid purposes.

26. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry, and that healthcare professionals remain free of conflicts of interest that could impact treatment decisions.

27. To ensure compliance, every federally-funded health care program requires every provider or supplier, as a condition of reimbursement, to ensure, and in some cases certify, compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

28. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that "[a]n AKS violation that results in a federal health care payment is a per se false claim under the FCA." *United States ex rel. Lutz v. Bluewave Healthcare Consultants, Inc.*, 853 F.3d 131, 136 (4th Cir. 2017); 42 U.S.C. § 1320a7b(g). The PPACA also makes clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." *Id.* at § 1320a-7(b)(h).

29. Courts have recognized that claims for reimbursement for medical care and items connected to and tainted by illegal kickbacks are "false" claims within the meaning of the FCA.[6]

30. Knowingly providing kickbacks to Prescribers or healthcare professionals to induce them to prescribe or recommend a drug (or to influence Prescriber prescriptions) to individuals who seek reimbursement for the drug from a federal Government healthcare program or causing

[6] *See, e.g., United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 315 (3d Cir. 2011); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011).

others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA.

31. A violation of the AKS constitutes a felony. Any party convicted under the AKS must be excluded from federal Government healthcare programs for a term of at least five years. 42 U.S.C. § 1320a-7(a).

32. Compliance with the AKS is required for reimbursement of claims from federal Government healthcare programs, and claims made in violation of the law are actionable civilly under the FCA.[7] Compliance with the AKS is thus a fundamental and material aspect of what the Government purchases when it pays for medical care for federally insured beneficiaries.

33. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute.[8] None of the statutory exceptions or regulatory safe harbors protect Defendants from liability for the conduct alleged herein.

34. Each of the Plaintiff States has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS. By engaging in the unlawful schemes alleged herein, Defendants not only violated the federal FCA and AKS, but also the state statutes embodying the FCA and the AKS.

AFFECTED GOVERNMENT HEALTHCARE PROGRAMS

35. Generally, when a Prescriber prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal healthcare program(s) for reimbursement.

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[7] *See* 42 U.S.C. § 1320a-7b(g)(stating, in part, that "a claim that includes items or services resulting from a violation of . . . [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]"); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011)(stating that "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare").

[8] *See* 42 U.S.C. § 1320a-7b(b)(3).

36. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal healthcare program purchases the drug directly rather than reimbursing the pharmacy.

A. Medicare

37. Medicare ("Medicare") is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled.[9]

38. Part D of Medicare was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006.

39. All persons enrolled in Medicare Part A or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies ("Part D sponsor(s)") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually-renewable contracts. Part D sponsors enter subcontracts with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

40. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"),

[9] *See* 42 U.S.C. §§ 1395 *et seq.*

which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

41. Payments to a Part D Plan sponsor are "conditioned upon the provision of information to CMS that is necessary" for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage.[10] CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the required data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

42. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor's plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies.[11] At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS

[10] *See* 42 C.F.R. § 423.322.
[11] *See* 42 C.F.R. §§ 423.315, 423.329.

reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages.[12]

43. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund.[13]

44. To receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

45. By statute, all contracts between a Part D Plan sponsor and HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program.[14]

46. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS.[15]

47. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with…federal laws and regulations designed to prevent…fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729, et seq.), and the anti-kickback

[12] *See* 42 C.F.R. § 423.336.
[13] *See* 42 C.F.R. § 423.315(a).
[14] *See* 42 U.S.C. § 1395w-112(b)(1).
[15] *See* 42 C.F.R. § 423.505(h)(l).

statute (§ 1127B(b) of the Act)."[16]

48. CMS regulations further require that all subcontracts between Part D Plan sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions.[17]

49. A Part D Plan sponsor is also required by federal regulation to certify to the accuracy, completeness and truthfulness of the DE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment . . . , the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
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> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.
>
> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under§ 423.87l(f)) are accurate, complete, and truthful and acknowledge

[16] *See* 42 C.F.R. § 423.505(h)(1).
[17] *See* 42 C.F.R. § 423.505(i)(4)(iv).

> that the claims data will be used for the purpose of obtaining Federal reimbursement.[18]

50. Compliance with the regulatory requirement that the PDE data submitted to CMS be "true, accurate, and complete" is a condition of payment under the Medicare Part D program.[19]

51. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between [CMS] and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the

[18] *See* 42 C.F.R. § 423.505(k).
[19] *See Id.* § 423.505(k)(1).

> prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

52. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

53. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement."[20]

54. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. To be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the AKS, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the

[20] *See* 42 C.F.R. § 423.505(k)(3).

"Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity

55. Lastly, when submitting a claim using the CMS claim form, the provider certifies that the claim, whether submitted by the provider or on the provider's behalf, "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute. . . ." Moreover, the provider certifies that the services claimed "were medically necessary and personally furnished by [the provider] or were furnished incident to [the provider's] professional service. . . ."[21]

B. Medicaid

56. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program.

57. The federal Medicaid statute requires each participating state to implement a plan

[21] Centers for Medicare & Medicaid Services, *CMS 1500-Health Insurance Claim Form*, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last accessed, Nov. 1, 2018).

containing certain specified minimum criteria for coverage and payment of claims.[22]

58. While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

59. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average.[23] Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal Government pays to the state the statutorily established share of the "total amount expended ... as medical assistance under the State plan."[24]

60. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs.

61. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures).[25]

62. Claims arising from illegal kickbacks are not authorized to be paid under state

[22] *See* 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).
[23] *See* 42 U.S.C. § 1396d(b).
[24] *See* 42 U.S.C. § 1396b(a)(l).
[25] *See* 42 C.F.R. § 430.30.

regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

63. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and regulations.

64. For example, in New York, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished, [. . .] will be subject to the following certification . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

C. TRICARE

65. TRICARE is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents.

66. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit

program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

67. TRICARE prescription drug benefits are provided through three different programs: (i) military treatment facility outpatient pharmacies; (ii) TRICARE network retail pharmacies; and (iii) TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In-addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies, and submit a claim for reimbursement directly with TRICARE's pharmacy benefits managers ("PBM"). The claims process is different for each of these pharmaceutical programs.

68. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

69. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE/DOD.CHAMPUS Medical Claim - Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

70. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any applicable co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals after accumulated dispensing reach full package size amounts. The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. DLA bills TRICARE directly for drug replenishment costs.

71. Pursuant to 38 U.S. C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least

24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

72. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

73. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

74. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions.[26]

75. TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied.[27] Kickback arrangements are included within the definition

[26] *See* 32 C.F.R.§ 199.9(a)(4).
[27] *Id.* § 199.9(b).

of abusive practices that constitute program fraud.[28]

D. Veterans Administration Health Care

76. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

77. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule ("FSS") program. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price. A VA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor ("PPV") for distribution of pharmaceuticals.

78. Since May 10, 2004, McKesson Corporation has served as the VA's PPV. The PPV fills the order for the facility, and then submits an invoice to the VA for payment, charging the VA the price set by the contract awarded by the VA to the drug manufacturer. The VA makes payment to the PPV. The PPV then seeks a chargeback from the drug manufacturer for any difference between the contract price paid by the VA and the PPV's acquisition price.

[28] *Id.* §§ 199.2(b), 199.9(c)(12).

79. Pursuant to the PPACA, among other things, all claims to Government reimbursed programs resulting from a violation of the AKS are also a violation of the FCA.

80. Moreover, the statutes and regulations set forth above concerning Medicare, Medicaid, TRICARE and Veterans Administration Health Care (collectively, the "Federal Healthcare Programs"), when viewed together, state that healthcare providers must comply with the AKS for claims they cause to be submitted to these programs to be reimbursed.

81. Here, the claims submitted for Rebif violated the AKS because they stemmed from prescriptions that were tainted by kickbacks, while the participants in the scheme knew that claims for reimbursement would be submitted to the above Federal Healthcare Programs. As such, and as more fully discussed below, the prescribing healthcare providers – expressly and impliedly – falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, TRICARE, and Veterans Administration Health Care.

82. In addition to falsely certifying compliance with the AKS, the healthcare providers also falsely certified compliance with the contractual provisions of those programs that were conditions for payment.

83. As detailed herein, the Drug Companies devised and implemented unlawful schemes in concert with the Consultants through which they (i) gave kickbacks to third party "educators" hired through the Consultants to induce those educators to recommend providers prescribe Rebif, and (ii) provided free in-kind support services to providers to induce those providers to prescribe the Covered Drugs.

84. Knowingly paying kickbacks to induce physicians to prescribe a drug on-label or off-label (or to influence physician prescriptions) for patients who seek reimbursement for the drug from a Federal Healthcare Program or causing others to do so, while certifying compliance with

the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and similar state False Claims Acts.

RELATOR'S INVESTIGATION

85. To unmask Defendants' unlawful conduct, Relators and its representatives conducted a rigorous, multi-faceted investigation which included the following:

(1) Comprehensive industry research into unlawful industry practices;

(2) Interviews with numerous individuals with direct knowledge of and involvement in Defendants' fraudulent schemes;

(3) Independent industry research regarding the planning, implementation and execution of Defendants' fraudulent schemes;

(4) Examination of Prescriber-specific Medicare data; and

(5) Examination of product-specific Medicare and Medicaid data.

86. Among the many individuals interviewed, the following individuals provided significant knowledge and insight into Defendants' fraudulent schemes:

(1) Jean Powers (Powers) was employed by Serono as a Key Account Manager from approximately February 2013 through October 2013 and then again February 2015 through March 2016. Her territory included Western Illinois and the Milwaukee, Wisconsin region.

(2) John McCann (McCann) was employed by Serono as a Case Reimbursement Specialist from approximately March 2016.

(3) Carmen Kosicek (Kosicek) was employed by Quintiles as a Rebif nurse educator from approximately October 2013 through June 2014. Her territory included Tennessee.

(4) Susan Wopperer (Wopperer) was employed by Quintiles as a nurse educator from approximately 2012 to the present. Her territory included New York.

(5) Bethany Boland (Boland) was employed by Quintiles as a Rebif nurse educator from approximately March 2011 to July 2012. Her territory was Connecticut and Massachusetts.

(6) Karen Campione (Campione) was employed by RXC as a Rebif nurse educator from 2013 to the present. Her territory was south-eastern Pennsylvania and southern New Jersey.

(7) Lauran Donofrio (Donofrio) was employed by RXC as a Rebif nurse educator beginning in 2014 to the present. Her territory was the state of Florida.

(8) Tracie Sloui (Sloui) was employed as a Rebif nurse educator by Quintiles from 2009 to 2013 and employed by RXC from October 2013 to July 2014. Her territory was Syracuse and Albany, New York and the surrounding area.

(9) Barbara Van Asdian (Van Asdian) was employed by Quintiles as a Rebif nurse educator from 2007 to September 2013. Her territory was Salt Lake City, Utah and the surrounding area.

87. Given their years of relevant experience, nurse educators Kosicek, Wopperer, Boland, Campione, Donofrio, Sloui, and Van Asdian were familiar with many aspects of Defendants' unlawful schemes, as detailed herein. While their job responsibilities and tasks may have differed slightly and may have covered only particular aspects of Defendants' conduct, the individuals interviewed by Relators had general knowledge about the overall unlawful fraudulent schemes.

88. Relators have conducted numerous interviews regarding Pharmaceutical industry practices.

89. Moreover, as part of its investigations into the Defendants' unlawful conduct, Relators conducted data analytics using a private healthcare data vendor that aggregates both public and private healthcare data. Through this vendor, Relator has access to and can analyze claims data for Medicare Part D Prescription claims, with nationwide coverage from 2013 – 2016 and is updated annually. Said claims data provides information on prescription drugs prescribed by individual physicians and other health care providers and paid for under the Medicare Part D Prescription Drug Program. This file is based on information from CMS's Chronic Conditions Data Warehouse, which contains Prescription Drug Event records submitted by Medicare Advantage Prescription Drug ("MAPD") plans and by stand-alone Prescription Drug Plans ("PDP"). The dataset identifies providers by their National Provider Identifier ("NPI") and the specific prescriptions that were dispensed at their direction, listed by brand name (if applicable) and generic name. For each prescriber and drug, the dataset includes the total number of prescriptions that were dispensed, which include original prescriptions and any refills, and the total drug cost. The total drug cost includes the ingredient cost of the medication, dispensing fees, sales tax, and any applicable administration fees and is based on the amount paid by the Part D plan, Medicare beneficiary, Government subsidies, and any other third-party payers.

90. Finally, Relators have aggregated data from various State Medicaid providers. These data sources give Relators significant insight into prescription drug utilization over a multi-year period.

DEFENDANTS' FRAUDULENT SCHEMES

91. Based on Relators' investigation and analysis, Relators have uncovered evidence that Pfizer and Serono, with significant assistance from RXC and Quintiles, engaged in three illegal schemes by giving something of substantial value to Prescribers for the purpose of inducing recommendations and prescriptions of Rebif to patients.

92. In the first scheme, Pfizer and Serono contracted with and paid remuneration to RXC and Quintiles to deploy "white coat" nurses to act as undercover sales agents to recommend Rebif to Prescribers and patients, thereby blurring the lines between independent medical advice and sales.

93. In the second scheme, with assistance from RXC and Quintiles, Pfizer and Serono provided the services of skilled nurses, for free, in part to induce Prescribers to recommend Rebif to their patients.

94. In the third scheme, with assistance from RXC and Quintiles, Pfizer and Serono provided in-kind remuneration in the form of free reimbursement support services, saving Prescribers thousands of dollars in administrative expenses, to induce Prescribers to recommend Rebif to their patients.

95. The following sets forth the illegal schemes that the Drug Companies and Consultants engaged in to increase the Drug Companies' Rebif sales and profits at the Government's expense.

A. FIRST SCHEME: DEFENDANTS' UNLAWFUL "WHITE COAT MARKETING" WITH NURSE EDUCATORS

The Background of the Unlawful "White Coat Marketing" Scheme

96. In its first scheme, "*White Coat Marketing Scheme*," the Drug Companies, with the

assistance from Quintiles and RXC, improperly engaged in "White Coat Marketing" by capitalizing on the clinical status of skilled registered nurses to obtain superior access to Prescribers to promote Rebif to Prescribers and induce Prescribers to prescribe Rebif to their MS patients.

97. This scheme was designed and intended to gain better access to Prescribers and leverage this access into sales.

98. Relator's investigation revealed that this scheme arose because Prescribers often restrict or deny access to drug reps,[29] but are naturally inclined to meet with and listen to healthcare professionals, such as registered nurses. Accordingly, with support from Quintiles and RXC, Serono and Pfizer created a scheme where registered nurses purported to provide independent medical advice to Prescribers and patients. However, in reality, the Quintiles and RXC nurses were undercover sales agents paid to promote and recommend Rebif to Prescribers and patients.

99. The scheme plainly involved the furnishing of cash consideration in return for services that led to Rebif prescriptions being filled and paid for with Government money. That consideration was paid by Serono and Pfizer to Quintiles and RXC to deploy nurses in the manner set forth herein. Although the precise amount paid each year by Serono and Pfizer is not known to the Relators, its industry research reveals that the consideration is in the tens of millions of dollars each year. By paying and accepting remuneration to recommend products that were subsequently reimbursed by Government Healthcare Programs, Serono, Pfizer, Quintiles and RXC

[29] According to AccessMonitor™, the number of "rep-accessible" physicians – that is, the number of physicians who meet with more than 70 percent of sales reps who attempt to meet with them — dropped to 44 percent from 46 percent in 2015. 44 percent of physicians are "accessible" (that is, they met with more than 70 percent of sales reps who try to meet with them). By comparison, in 2008, nearly 80 percent of physicians met with most reps;38 percent of physicians restricted access (that is, they met with 31 to 70 percent of reps who try to meet with them);18 percent of physicians "severely" restricted access (that is, they meet with 30 percent or fewer reps who try to meet with them). *See* World of DTC Marketing.com, *Doctors Continue to say "no" to pharma reps* (Sept. 28, 2016), *available at* http://worldofdtcmarketing.com/doctors-continue-say-no-pharma-reps/marketing-to-health-care-professionals/ (last accessed Nov. 21, 2018).

violated the AKS.

100. The Office of Inspector General ("OIG"), which coined the term "White Coat Marketing," has expressly warned against it:

> The fraud and abuse risks are compounded where . . . a physician or other health care professional is involved in the marketing activity—a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services . . . .[30]

101. The OIG specifically warned against the White Coat Marketing because it leads to overutilization and increased costs to Federal Healthcare Programs:

> These marketing activities are highly susceptible to fraud and abuse, as they can lead to overutilization, increased costs to the Federal health care programs and beneficiaries, inappropriate medical choices, and adverse effects on the quality of care patients receive.[31]

102. In and/or around 2006, the Drug Companies entered into agreements with the Consultants pursuant to which the Drug Companies would pay the Consultants in exchange for the Consultants deploying their Nurse Educators to gain access to Prescribers to market the Drug Companies' drug.

103. The Drug Companies knew that its target Prescriber base (i.e., primary care physicians and neurologists) frequently refused to meet with its drug reps regarding the Drug Manufacturers' MS drug. The Drug Companies sought to overcome those barriers by employing the unlawful White Coat Marketing scheme through its relationship with the Consultants.

104. The Drug Companies also knew that Nurse Educators were viewed by Prescribers

[30] *See, e.g.*, Department of Health and Human Services, *OIG Advisory Op.* 11-08, at 6 (Jun. 14, 2011), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf (last accessed Nov. 5, 2018).
[31] *See id.*

as more credentialed and thus more credible than the Drug Companies' drug reps. As expert clinicians, the Consultants' Nurse Educators were more likely than drug reps to gain access to providers because they could talk on a "peer to peer" level with providers regarding MS.

105. Because the Nurse Educators were clinicians and not intended to appear as drug reps, the Drug Companies needed a clever and nuanced approach to disguise this fraudulent marketing strategy.

106. The Drug Companies knew that Nurse Educators could not openly appear to act in the role of drug reps for several reasons. One, the Drug Companies feared that if Prescribers *knew* that the Nurse Educators were intended to be part of the Drug Companies' sales team, Prescribers would limit Nurse Educator access in the same manner that Prescribers limited the access of drug reps. Two, if the Drug Companies openly admitted that Nurse Educators were promoting its drugs, the Drug Companies would be forced to lawfully restrict the Nurse Educators' messaging to only Food and Drug Administration ("FDA") approved marketing materials or risk a charge of "off label" promotion. Lastly, the Drug Companies were aware that the OIG considers this "white coat" marketing (i.e., utilizing clinicians to promote and sell drugs) as particularly suspect. The Defendants feared that if their efforts appeared too brazen, it would attract HHS-OIG detection.

107. As a result, the Drug Companies created a contrived MS disease awareness program that disguised the true function of the Nurse Educators, and made Nurse Educators appear to be functioning distinct and independent from the role of the drug reps.

108. To accomplish this goal, the Drug Companies designated the nurses as "educators" who, instead of being paid to sell the drugs, were purportedly tasked with marketing and promoting the free MS educational services to Prescribers and patients.

109. Despite using a "form-over-substance" labeling of the Nurse Educators, the Nurse

Educators were trained and deployed to function as drug reps by every measure except title.

110. Specifically, Serono and Pfizer utilized the Defendant Consultants for their much heralded "market special access" expertise to help promote Rebif. In other words, Serono and Pfizer retained the Consultant Defendants' nurses specifically because, as expert clinicians, they stood in a better position to access and influence the potential and current Prescribers than Serono/Pfizer's sales reps alone.

111. RXC boasts about the "special access" to physicians' offices that their nurse educators hold over sales reps:

> Nurse educators provide in-office clinical consultation to physicians to introduce new therapies (or changes to existing therapies), review administration procedures for injectable/IV products, and demonstrate medication preparation. In addition, **these clinicians provide access to offices which may be difficult for your sales representatives to engage**.
>
> - In-office clinical consultation
> - Introduce new (or review changes to existing) therapies
> - Review administrative procedures
> - Demonstrate medication preparation
> - **Connect sales team to 'closed door' practices**[32]
>
> (emphasis added).

112. The intended purpose of the Consultants' white coated nurse educators, easily confused with physicians or physician nursing representatives, to serve as undercover sales reps for the Drug Companies could not be more apparent.

113. The Drug Companies paid the Consultants tens of millions of dollars for the Nurse Educators force.

114. Underscoring the Nurse Educators' intended sales role, each of the Consultants'

[32] RXCrossroads, *Field Force*, *available at* https://www.rxcrossroads.com/solutions/field-force (last accessed Nov. 20, 2018).

Nurse Educators underwent the Drug Companies' specialized sales training programs, learned the Rebif sales "pitch," and practiced sales techniques before going out to visit with Prescribers. These programs were multiple day sales training events similar to those that were created for the drug reps. During these trainings, the Nurse Educators would learn sales techniques, sales objectives and strategies likely to influence prescribers, both potential and active, patients and patient families and caregivers. The Rebif White Coated nurse force essentially served to supplement Rebif's sales rep force and further drive up Rebif sales.

115. After completing the sales training, Defendants deployed the nurses across the country to target and infiltrate potential Prescriber offices and facilities. The nurses worked in close coordination with Serono and Pfizer's sales reps to promote Rebif. At the day-to-day level, this typically involved each territory's nurses and pharmaceutical sales reps coordinating calls based on prescribing data.

116. Serono and Pfizer trained the sales reps and nurse promoters to be product messaging experts. The initial goal was to get the first prescription – or even to convince a Prescriber to start the patient on a sample of the drug. Thereafter, each time the nurse promoter and sales rep interacted with that Prescriber's office, the goal was to seek out the Prescriber's experience with the patient's outcomes (i.e., did the drug work as advertised). Typically, that outcome information could only come from the patient. Yet, by using a nurse promoter – someone who was directly managing the patient so the Prescriber would not have to – the Rebif nurse would then return to the Prescribers' office and take the time to explain, in detail, in the full context, what the drug does, how it would be performing, why it is the best, and how the Prescriber can further use the drug in his/her practice. Because of the direct interaction between the Nursing Educator and the patient, it invited confusing interactions between the patient and Nursing Educator, where

the patient shared concerns with someone who presented as a physician's agent, but was incentivized to suppress, filter, channel or blunt patient care concerns about the drug's performance or side effects to the Prescriber.

117. Serono and Pfizer mandated these nurse promoters to focus solely on Rebif, to the exclusion of competitor products that may have been better suited for particular patients. This highlights the insidious nature and dangers of White Coat Marketing. The incentives offered by Serono and Pfizer to the Quintiles and RXC nurses directly conflict with the nurses' duty to their patients, such as discussing *all* available options to treat each patient's disease. Because nurse promoters were not permitted to discuss courses of treatment that did not involve Rebif, the nurses abdicated their role as "educators" and, despite being experts on the diseases and the drugs that treat it, they were pressed to withhold potentially important information from patients and Prescribers.

118. Nurse Educator Van Asdian described her White Coat Marketing practice with Prescribers as a Rebif Nurse Educator. Van Asdian's White Coat Marketing involved going directly to a doctor's practice with drug reps: "what I did was I went around with the drug reps" to market Rebif to the doctors and their staff.

119. In some instances, Van Asdian personally knew the doctors and their nurses from prior dealings in the healthcare industry. For instance, prior to becoming a Rebif nurse educator, Van Asdian was a nurse practitioner and previously worked at the University of Utah. While there, Van Asdian was introduced to Julia Klein, who at the time was undergoing training to become a nurse practitioner. Later, when Van Asdian became a Rebif nurse educator and traveled with drug reps to physician practices to promote Rebif, Klein recognized Van Asdian from their prior relationship at the University of Utah. Van Asdian advised drug reps that "[look] 'I know this

person,' and they still wanted me to go with them, and that way it was a formal way of being introduced because I was in a different role." Considering their prior history together, Van Asdian managed to garner special access to Prescribers with whom she was already familiar.

120. Such prior dealings provided nurse educators, including Van Asdian, with an even greater advantage and access to Prescribers. The familiarity among healthcare professionals in a given region established a sense of trust among the doctors and nurse educators and personalized the marketing process, thereby, increasing the likelihood that such Prescribers recommended and prescribed Rebif to their MS patients over competitor drugs.

121. Nurse Educator Carmen Kosicek experienced a classic "White Coat Marketing scheme" as a Rebif Nurse Educator.

122. Kosicek was hired by Quintiles in and around October 13, 2013 and at first, her job was to educate, support and care for MS patients who were using Rebif. In many respects, she described her role as a traditional clinical one – caring for patients. However, she explained that once hired, within months that clinical role was expanded to include promoting Rebif like sales reps. Kosicek had previous experience as a sales rep prior to working at Quintiles and explained the different job responsibilities of each. Kosicek was told by her management that she was now required to call on neurology offices because Rebif sales reps were being turned away by providers who would not see sales reps.

123. Kosicek detailed her experience in "White Coat Marketing" for Rebif. She explained that when making sales calls to Prescribers, she was expected to talk to the doctors, specifically, and not the nurses. She explained that she was required to go over the product information with the doctor and explain why Rebif is better than competitors' drugs/therapies. She says the fact that she was a salesperson was "clearly obvious."

124. Kosicek further explained that one way to gain access to Prescribers and increase sales was to parlay her role as a nurse caring for that Prescriber's patients. Specifically, unlike a sales rep who would obviously call on Prescribers in order to promote Rebif, Kosicek would instead call on the Prescriber with a very different message that she was the nurse taking care of patients on Rebif. She and other nurses would do so under the guise of giving an "injection report" about a specific patient to the doctor. She could then "piggyback" a sales pitch to the injection report. Besides explaining the injection report, she would provide clinical information about the patient, for instance: if the patient was a hoarder (another neurological issue) or if the patient had problems with gait. Kosicek basically analyzed the patient's home life and provided the doctor with information that the Prescriber otherwise would not have access to by providing only traditional in-office medical care to the patient. According to Kosicek, the doctors were happy to have a healthcare provider caring for their patients at home. She informed that "it really doesn't matter about the product at this point" because "the provider realizes that if he prescribes Rebif, nurse educators can assess the patient and give the doctor an update."

125. Generally, when treating an MS patient, Kosicek explained that Prescribers would typically give patients a choice of six products that treat MS. Most Prescribers would explain to the patient that all the medications work and all of them are approved by the FDA. However, as part of the Rebif sales pitch, the nurse educator and sales force would also encourage the Prescribers to choose Rebif because patients were also getting the benefit of nurses available to train, manage and care for the patient at the patient's home. She stated that it was her experience that patients and Prescribers wanted the extra benefit of a nurse in choosing which drug to treat MS.

126. Kosicek further detailed her personal experience with White Coat Marketing. She

would sit in the waiting room as any other sales rep and wait to see the doctor. She was equipped with an iPad-like device where there was a flip-through marketing piece. She recalls that there were four or five slides that were periodically changed. These slides included different talking points, and they were branded slides that detailed the product. Kosicek would have to get a "box checked," including an electronic signature by the doctor, on the iPad like device at the conclusion of her sales pitch. Further, Kosicek entered her sales call information into a computer program called "Viva."

127. Kosicek explained the difference between a nurse and a sales rep is "night and day." A healthcare provider such as a nurse is respected by the other healthcare providers such as doctors and other nurses. Nurses are trusted, so any message from a nurse is taken in a different light than if the same message came from a sales rep. Moreover, a nurse can answer intelligent, medical questions for the doctor better than a sales rep could. Reflecting, she expressed a belief that nurse educators in sales are making a "mockery" in claiming that their role is about education. The pitch that she gave doctors was "the exact same pitch as the sales rep." However, the one advantage was that sales reps "parrot" what the Drug Companies trained them to say while the nurse educators can use their health and medical training to answer any question that deviates from what the sales reps were trained to say.

128. Kosicek expressed a belief that the Rebif nurse educators positively impacted increasing prescriptions for Rebif. She recalled Rebif sales reps boasting about their large bonuses. She explained that a big prescriber provided about ten prescriptions per month; thus, an increase of just three prescriptions was significant.

129. In Kosicek's own words, the Rebif nurse educators were engaged in "down right sales." Kosicek recalls siting in a doctor's office preparing to make a sales pitch to a doctor when

one of her patients walked in to whom she had provided injection training. She recalled vividly how conflicted she felt because of the care she owed to that patient, but simultaneously, as a Rebif nurse educator, she felt compelled to sell Rebif to that patient's doctor.

130. Nurse Educator Susan Wopperer's experience with White Coat Marketing mirrored that of nurse Kosicek. Wopperer explained that her job undoubtedly involved sales and she believes that "it's easier" to get the attention of Prescribers' staff because she is a nurse and not a sales rep. Nevertheless, Wopperer explained that the "key account manager" (Rebif salesperson) typically goes to the office first and usually sets up the introduction to take place at a lunch and learn. Wopperer confirmed that she is more likely to get a prescription after holding an office lunch. However, Wopperer also makes sales calls on her own and generally introduces herself as a field nurse that sees patients taking Rebif. She explained that if the doctor's office has one patient on Rebif and she performed training for that patient, she could go back to the provider's office under the auspices of giving the Prescriber an injection report about the patient. That report was her "hook" for getting back into the office.

131. Once back in offices, Wopperer would then parlay the injection report into sales pitch opportunities. Wopperer's pitch consisted of outlining the Nurse Education and Reimbursement Support Services Rebif offers to doctors and their staff. Wopperer stated that she and the other white coated nurse marketers and sales reps promote Rebif along with the "extensive nurse services" to differentiate Rebif from its competitors. Wopperer believes Rebif has a competitive advantage over competitors because she believes those competitors may only provide limited support services while Rebif nurses can continue to treat the patient beyond the initial injection training. According to her, "our services never end." She has seen patients for 10 years. Thus, in promoting Rebif, Prescribers are sold not just on the drug's efficacy, but also on nurse

services that are at "no cost."

132. As a nurse educator, the majority of Wopperer's work involves working directly with the Rebif patients (set out more fully in the *Free Nurse Services Scheme* section). However, the balance of her time is spent promoting Rebif. She does so in a manner detailed above, but also providing staff training in the form of "in-services." In-services involves making office nurses aware of what Serono's nurse educators can do for the practice and training staff in doctor's offices, including medical assistants and nurses, on topics such as Rebif injection devices as there are three methods of injecting the drug. She explained that although office staff are generally aware of the drug, they are usually not aware of the "ins and outs" of the drug. She also provides "pretend skins" so office staff can have hands-on experience performing the injection themselves. She stated she also goes into Prescribers' offices to discuss Rebif clinical trials, medication efficacy and disease progression as well as show staff how she would educate the patient.

133. In addition to promoting the efficacy of the drug, she also promotes to the staff how she can "be an extension of the doctor's office" and "assess and evaluate" the patient.

134. She also stated that, in her experience, Prescribers like to allow their MS patients to choose which drug they will be on and part of the messaging is the free nurse program that provides patient support to assist them in staying adherent. In her opinion, because the Rebif nurse educators provide more patient support than competitor drugs' nurse educators, it serves as a competitive market advantage for Rebif.

135. Kosicek's and Wopperer's experience demonstrates the extent to which Rebif's "White Coated" nurse educators served as a powerful marketing tool and sales force in promoting and increasing the overall sales of Rebif nationwide.

136. Relators' investigation also revealed that the nurses, in order to further the sales

process, were trained to use a sales call note portal system (believed to be sales forces and/or Viva) to meticulously record each encounter with a target Prescriber. Thus, the defendants would have detailed electronic call records peculiarly in its control each time a Nurse promoted Rebif to a Prescriber. These electronic records are maintained by the Defendants in the ordinary course of its business. The electronic records would show each Prescriber's office who was targeted for White Coat Marketing, the nurse who marketed to that Prescriber's office, and the dates the promotion was performed and the results of that promotion.

137. Overall, the White Coat Marketing scheme was hugely successful as the Drug Companies' gained much-coveted "access" to potential and current Prescribers and their patients by using the Consultants' Nurse Educators. After gaining this access under the auspices of it being solely an education service, the Consultants' Nurse Educators ("white-coated" clinicians recognized by the industry as experts in MS treatments) were ideally positioned to exclusively recommend Rebif to Prescribers and, more troubling, directly to patients.

138. The Drug Companies trained and directed the Consultants' Nurse Educators to directly promote Rebif to Prescribers and patients once Nurse Educators gained access to and were positioned to recommend Rebif to Prescribers.

139. Through the infiltration of Prescriber offices and seemingly "educating" Prescribers on Rebif, nurse educators were able to influence Prescribers and patients and drive sales and profits for Defendants.

140. Not only was the White Coat Marketing program an integral part of the Drug Companies' overall strategic marketing for Rebif, but it also served as an especially effective marketing tool because it afforded the Drug Companies access to Prescribers that drug reps would not have otherwise enjoyed on their own and allowed the nurse educators to establish a direct

relationship with Prescribers.

141. In sum, Serono and Pfizer's nurse "educator" program was nothing more than a sophisticated marketing scheme to drive Rebif prescriptions and sales. By providing remuneration to Quintiles and RXC to deploy "white coated" nurses as undercover sales agents to recommend Rebif to Prescribers and patients, the Defendants violated the AKS.

142. During his tenure, Relator Harris worked with two Rebif nurses. Nurse Sheila Birch with whom he worked for most of his time and Nurse Patrice Harris (no relation) with whom he worked the last part of this tenure. In the manner set out above, these two nurses engaged in White Coat Marketing to the following Prescribers: Dr. Mitzi Williams; Dr. Jeffrey English; and Dr. Robert Gilbert from the MS Center in Atlanta; Dr. Ben Thrower; Dr. Cheryl Lorring; and Dr. Guy Buckle of the Sheppard Center; and Dr. Reinaldo Verson of the Columbus MS Center.

143. Relators' investigation revealed that Nurse Van Asdian engaged in White Coat Marketing in the manner identified herein. Her White Coat Marketing was targeted to several key Utah Prescribers as follows: Dr. Jeffrey Groves; Nurse Practitioner Julia Klein; Dr. Denise Skuster; Dr. John Rose; and, Dr. Joseph Watkins.

144. Relators' investigation also revealed that Nurse Tracie Sloui engaged in White Coat Marketing in a manner similar to what is set forth herein. Her White Coat Marketing was targeted to several New York prescribers as follows: Nurse Practitioner Jeanne Ceballos; Dr. Keith Edwards; Dr. Burk Jubelt; Nurse Practitioner Pamela Kirch; and, Dr. Hassan Shukri-Mahmod.

145. Relators' investigation also identified Nurse Campione who was engaged in White Coat Marketing in a manner similar to what is set forth herein. Her White Coat Marketing was targeted to several Pennsylvania and New Jersey Prescribers as follows: Dr. Syed Jaffery; Dr. Thomas Mirsen; Dr. Manzoor Abidi; Dr. Ravi Dukkipati; Dr. Thomas Leist; and, Dr. Dina Jacobs.

146. Relators' investigation also identified Nurse Boland who was engaged in White Coat Marketing in a manner similar to what is set forth herein. Her White Coat Marketing was targeted to Several Connecticut and Massachusetts Prescribers as follows: Dr. Derek Smith and Physician's Assistant Stacey Panasci.

147. The AKS proscribes this conduct, i.e., payment or offer of payment to "any person" in exchange for a recommendation or referral. It is immaterial if the payee receiving the remuneration in exchange for recommending a drug is a doctor (who can recommend by writing a patient a prescription) or some other payee, such as a nurse, a medical assistant, a patient recruiter, or a runner, who can recommend the drug to a patient or a Prescriber. By compensating the Consultants to deploy their Nurse Educators to influence Prescribers to increase recommendations and prescriptions for a drug paid for by the federal Government, the Drug Companies, as the payor, and the Consultants, as the payee, violated the AKS.

The Individuals Involved in the White Coat Marketing Scheme

148. As with the Free Nurse Educator Services developed by Serono and Pfizer detailed above, numerous Serono and RXC employees were involved in the design, approval, and implementation of the White Coat Marketing scheme to promote and boost Rebif sales, including but not limited to:

Name	Employer	Title/Dates of Employment	Role
Anissia Todd	Serono	Key Account Manager of Neurodegenerative Diseases: 03/2008 – 10/2012 Thought Leader Liaison of Neurodegenerative Disease and Immunology: 10/2012 – present	Developed the Rebif Free Nurse Educator and Support Services Programs to promote Rebif to healthcare professionals.

Name	Employer	Title/Dates of Employment	Role
Antonella Moretti	Serono	Director Rebif Strategic Marketing: 05/2018 – present Associate Director of Rebif Strategic Marketing: 01/2017 – May 2018	Directed marketing team for Rebif and oversaw the White Coat Marketing programs leveraged through Support Services and Free Nurse Educator Programs.
Azita McDermott	Serono	Rebif Product Manager of Neurodegenerative Diseases: 08/2009 – 09/2012 Associate Director of Rebif Marketing: 10/2012 – present	Developed Rebif marketing strategies and tactics, including implementing the White Coat "nurse liaison" programs, developing speaker programs, and increasing awareness of Rebif Support Services to Prescribers.
Christof Marre	Serono	Senior Director of Global Strategy and Franchise Operations: 07/2013 – 12/2015 Vice President of Global Brand Leader Rebif: 01/2016 – present	Provided Rebif consulting services, including the White Coat Marketing program, planning, growth strategies and development of Rebif.
Christopher Alfieri	Serono	Thought Leader Liaison	Involved with designing and implementing Rebif marketing delivered through the White Coat Marketing scheme.
Sheri Cohen Zabolotsky	RXC	Sales and Marketing Product Coordinator: 06/2012 – 08/2014	Assisted pharmaceutical companies in executing marketing initiates involving the White Coat Marketing scheme.
David Schneider	RXC	Senior Director, Strategic Account Management, CVS Health: 08/2016 – present	Leads RXC's Strategic Account Team, which is responsible for building a mutually beneficial relationship with CVS pharmacies.

Name	Employer	Title/Dates of Employment	Role
Dorothy B. Brown	RXC	Director of Sales and Marketing: 05/2013 – present	Manages and oversees the promotional and marketing activity of the Rebif nurses engaged in the White Coat Marketing scheme.

149. The White Coat Marketing scheme was implemented and delivered by RXC and Quintiles nurses that administered the Free Nurse program.

150. The above-mentioned individuals played significant roles in designing, developing and implementing the unlawful White Coat Marketing scheme with the singular goal of increasing Rebif prescriptions and sales.

The Duration of the White Coat Marketing Scheme

151. Relator's investigation establishes that the White Coat Marketing Scheme served as an integral part of the Drug Companies' efforts to promote and drive Rebif prescriptions and sales and, accordingly, has been administered continuously since being established by Serono and Pfizer in collaboration with Quintiles and RXC.

152. According to Nurse Wopperer, Quintiles and Sereno have contracted for Rebif nurse educators since approximately 2006 – and that the contract was recently renewed for three more years. Her understanding is that this is among the longest third-party contracts in the pharmaceutical industry.

153. Through Relator's investigation, Relator has learned that drug companies, including Serono and Pfizer enter into detailed contracts with vendors such as the co-Defendant vendors. These contracts are re-negotiated based upon the Drug Companies' "ROI" or return on investment of drug sales from the payments it makes to the co-Defendant vendors. Those contracts

include an attached Scopes of Work, referred to as "SOWs." The SOW for Serono and Pfizer's contract spells out in detail each discrete task that is to be performed and the payment that will be made for each. These contracts are not publicly available but are in the exclusive possession and control of the Defendants and will spell out the precise dates that the scheme began.

154. For instance, Antonella Moretti (Moretti) worked for Serono as Associate Director and presently as Director of Rebif Strategic Marketing from January 2017 through present in Massachusetts. During that time-frame and in collaboration with Pfizer, Moretti directed marketing of Rebif to Prescribers and oversaw the White Coat Marketing programs leveraged through the Nurse Educator and Reimbursement Support Services initiatives aimed at increasing Rebif prescriptions and sales.

155. Additionally, Azita McDermott (McDermott) worked for Serono as a Rebif Product Manager from August 2009 through September 2012 and later as Associate Director of Rebif Marketing from October 2012 through present in Massachusetts. In these roles, McDermott developed marketing strategies and tactics to promote Rebif to Prescribers particularly through deploying the white coated nurses to increase Prescriber awareness of Rebif Nurse Educator and Reimbursement Support Services.

156. Furthermore, Sheri Cohen Zabolotsky (Zabolotsky) worked for RXC as a Sales and Marketing Product Coordinator from June 2012 through August 2014. Zabolotsky assisted Serono and Pfizer in executing marketing initiatives and tasks involving the White Coat Marketing programs throughout Pennsylvania to promote Rebif.

157. As indicated by the list of individuals above, The White Coat Marketing Scheme dates back to at least 2006 through present.

The Geographic Span of the White Coat Marketing Scheme

158. The White Coat Marketing program is administered nationwide and is and was available to patients throughout the United States.

159. Relator's investigation reveals that the White Coat Marketing program has been implemented in every region of the United States and in almost all 50 states.

B. SECOND SCHEME: QUID PRO QUO KICKBACKS – FREE NURSE EDUCATOR SERVICES IN EXCHANGE FOR REFERRALS

The Background of the Unlawful "Free Nurse Kickback" Scheme

160. In its second scheme, the "*Free Nurse Kickback Scheme*," Serono and Pfizer contracted with RXC and Quintiles to deploy a force of Clinical Educators ("Nurse Educators") which provided free nursing, free patient education and free management services, to induce Prescribers across the United States to prescribe Rebif to patients over competitor MS drugs.

161. By way of background, Relator's industry research demonstrated that most Prescribers typically allocate between 10 to 15 minutes to see routine patients. But few MS patients are routine patients as they suffer from an array of chronic diseases requiring extra office time, training, follow-up care, and resources to manage their disease. For this reason, Prescribers frequently rely on their highly skilled and paid nursing staff – called "nurse educators" – to help manage and treat chronically ill patients. The cost associated with the use of these nurses, however, is significant. A nurse educator often commands an annual salary that exceeds $60,000, or an average hourly wage of $40.00 per hour.

162. Relator's industry research further uncovered that the Drug Companies, seeking to exploit the needs of Prescribers and healthcare organizations and the challenges they face in managing patients affected by chronic diseases, such as MS, developed a marketing strategy that

involved providing free nurses to Prescribers to induce them to prescribe Rebif to their patients. The scheme had the additional benefit of providing its Nursing Educators with better access and control of side effects reporting by patients.

163. Nurse Educators, who are licensed practical and registered nurses employed by Quintiles and RXC, are recognized as specialty clinicians with specialized training, education and experience in MS education and care. As clinicians with significant training, education and experience, Nurse Educators can command significant compensation in the healthcare workforce.

164. Nurse Educators are in significant demand by healthcare providers who care for MS patients, and many primary care and neurology practices directly employ Nurse Educators to work with their MS patients to educate them and their families about MS and its treatments.

165. Knowing that Nurse Educators were needed by most practices treating MS patients and seeking to exploit that vulnerability, Pfizer and Serono paid Quintiles and RXC to unlawfully promote its drugs using Nurse Educators to Prescribers to induce those Prescribers to prescribe Rebif to their patients. The Drug Companies were aware that Nurse Educators were respected by physicians as clinicians. For that reason, the Drug Companies specifically contracted with RXC and Quintiles to deploy Nurse Educators (over non-clinical sales reps) to effectuate this scheme.

166. This scheme arose because medical care for chronically ill patients does not stop after the diagnosis is made and a treatment regimen is selected. The relevant literature recognizes that Prescribers have a "duty to attend" to the patient throughout the course of treatment.[33] Thus,

[33] *See, e.g.*, T. Thirumoorthy, The Professional Duties of the Doctor in the Role of a Healer, SMA News, Aug. 2012, at 22 ("The doctor should continue to serve the patient and provide appropriate access to care in a timely manner. The doctor has an ethical and legal duty to attend as required by his patient's needs and should not delegate critical duties to juniors. If a doctor delegates duties to another clinician, he must ensure that the attending clinician is adequately informed and competent. The doctor should never abandon his patient . . ."); AMA Code of Medical Ethics Opinion § 1.1.3(b) ("Physicians can best contribute to a mutually respectful alliance with patients by serving as their patients' advocates and by respecting patients' rights. These include the right . . . [t]o receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment. Patients should be able to expect that their

whenever a Prescriber is treating a patient affected by MS or cancer, the Prescriber has an ongoing duty to the patient that continues throughout the course of treatment. This duty requires the Prescriber or his or her staff to consistently monitor the patient's response to medication, treatment, and vitality – a task that typically involves multiple telephone calls, office visits, and communication with the patient.

167. The duty to attend to the patient is substantial and presents significant challenges to healthcare providers. Chronic diseases such as MS and cancer are unpredictable and often disabling diseases, and their progression, severity, and symptoms can vary significantly from patient to patient. Case management can also be complex due to relapses and patient disease fluctuations. Furthermore, MS and cancer medications – including Rebif – are oftentimes associated with significant side effects that may require treatment or management. For instance, common side effects associated with Rebif include seizures, nausea, loss of appetite, tiredness, blood problems, thyroid problems, depression, anxiety, allergic and skin reactions, and flu-like symptoms such as fever, muscle pain, chills.[34] To manage these side effects, Prescribers may adjust the treatment dosage, prescribe medications that may lessen the side effects, or, at times, discontinue treatment in favor of other options.

168. While the treatment of MS requires Prescribers' continuous involvement post-diagnosis and the constant monitoring of the patients' reaction to and tolerance for treatment, following-up and monitoring patients are not profitable endeavors for Prescribers.

169. Most importantly, much of the required follow-up and monitoring work requires telephonic interactions. However, Prescribers are not allowed to bill patients' insurance –

physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment.").

[34] Rebif, *Possible Side Effects of Rebif*, *available at* https://www.rebif.com/taking-rebif/rebif-side-effects (last accessed Nov. 4, 2018).

including Medicare and other Government-sponsored plans – for phone interactions with patients. As a result, as market commentators have noted, "doctors' offices are struggling to man the phones: handling everything from appointment and prescription refill requests, to concerns from sick patients, to billing issues – and lately, more patients' questions about how the health reform law will affect them. But insurance carriers don't pay doctors for any of those phone calls, which doctors estimate cost $15 to $20 each. . . . Now, more offices and hospitals are looking for ways to take fewer patients' calls."[35]

170. And even in instances when the patients are able to travel to the Prescribers' offices for in-person follow-up, Medicare and other Government-sponsored plans usually pay a reduced rate for care administered by the Prescribers' staff.[36] Full rates are paid for staff's services only if the Prescribers are "present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services."[37]

171. Seeking to capitalize on the challenges and unprofitability that required patient monitoring and follow-up care presented to Prescribers and their staff, Serono and Pfizer, through Quintiles and RXC, devised the Free Nurse Educator program. To do so, the Drug Companies identified the unique and particular needs and challenges that MS care providers faced in managing their own practices and patients. Once these providers' needs and challenges were identified, the Drug Companies, through the Consultants, began offering these providers "solutions" to those

[35] *See* J. Wieczner, *The Doctor Won't Take Your Call: Physicians Hate Phone Calls, and Not Just Because They Can't Bill You*, MarketWatch, July 16, 2013, *available at* www.marketwatch.com/story/the-doctor-wont-take-your-call-2013-07-16 (last accessed Nov. 19, 2018); *see also Coding for Telephone Consultations*, Tex. Med. Ass'n, Mar. 23, 2010, available at https://www.texmed.org/template.aspx?id=5422 (last accessed Nov. 19, 2018)(noting that "Medicare does not reimburse" for, among other things, "telephone evaluation and management (E&M) service provided by a physician to an established patient, parent, or guardian not originating from a related E&M service or procedure within the next 24 hours or soonest available appointment").

[36] *See* G. John Verhovshek, *The Basics of Incident-to Billing*, *Physicians Practice*, Nov. 24, 2016, *available at* http://www.physicianspractice.com/medical-billing-collections/basicsincident-billing (last accessed Nov. 19, 2018).

[37] *See id.*

needs and challenges.

172. One significant problem that providers treating MS patients face is that MS patients are complex, and require multiple medications and extra training, time and resources to manage. Large provider practices specializing in MS care could afford to employ "in-house" Nurse Educators to work with and manage MS patients. Smaller providers, however, are much less likely to hire a Nurse Educator at a cost of $50,000 to $100,000 in annual salary or an average wage of $40.00 per hour or more. Without a Nurse Educator, the provider's office is strained to handle all the complexities of managing an MS patient without being able to bill payors separately for those services.

173. Consequently, starting in or around 2006, the Drug Companies began offering and then providing MS providers the time, service, expertise and resources of a Consultant-employed Nurse Educator to help manage that providers' MS patients and to provide MS training to the providers' staff. The Nurse Educators assist with practice efficiency, training on MS care, conducting at home sessions to teach patients how to perform injections, and serve as "on call" monitors to answer patient questions. In some cases, the Nurse Educators would also provide one-on-one training for patients, during which the Nurse Educators could manage patients.

174. The Drug Companies employed this force of Nurse Educators through the Consultants dedicated specifically to performing these nurse educator services with the overriding goal of increasing Rebif prescriptions and sales.

175. Rebif's support and reimbursement hub is called "MS LifeLines." MS LifeLines is an in-house service provided by EMD Serono to Rebif patients.

176. Serono highlights the significant role that its "MS LifeLines Nurse"[38] educators

[38] Serono refers to their nurse educators as "MS LifeLines Nurses." *See* Rebif, *One-on-One support*, *available at* https://www.rebif.com/rebif-one-on-one-support/nurses (last accessed Nov. 21, 2018).

play in promoting Rebif to MS patients:

> **All of the MS LifeLines Nurses are trained to help manage MS symptoms**. They are here to help you with your treatment and can answer any questions you may have about relapsing MS. In addition, they can:
>
> - **Offer information** about treating with Rebif® (interferon beta-1a)
> - **Provide tips** that may help manage certain side effects
> - **Recommend strategies** to help you stay motivated with therapy
> - **Provide ongoing telephone follow-up and much more**
>
> ***
>
> In addition to the MS-certified nurses available through the MS LifeLines call center, **a dedicated team of field nurses is available in many areas of the United States**. And although they may not be MS-certified, they are registered nurses who can help you in many ways.
>
> **They will come to your home and provide you with 1-on-1 training on proper injection techniques, review your Welcome Kit with you, and share tips that may help you deal with certain side effects**. [39]
> (emphasis added).

177. According to Relator Harris, MS LifeLines operates in the following manner:

> the doctor writes a prescription and it goes through MS LifeLines. **I use a list of prescribing doctors from MS Lifelines to target potential writers**. I ask a doctor why he chose Rebif and make sure patients' information goes into MS LifeLines. MS LifeLines works with insurance companies and prior authorizations to get coverage. I will then tell the doctor whether the drug is covered or not for the patient, and tell the doctor a nurse educator will train the patient. MS Lifeline has all of that information, and I know initials of patients. I will then report to the doctor after the nurse educator does the training to get feedback.
> (emphasis added)

178. Relator Panzey Belgium Harris (Harris) was employed by Pfizer as a Therapeutic Account Specialist from approximately January 2015 through June 2016. His territory included

[39] See *id.*

the Atlanta, Georgia region. According to Harris, the MS Center of Atlanta has three doctors that treat approximately fifty percent of all MS patients in the Atlanta, Georgia region.

179. Harris' Rebif training consisted of two or three weeks of home study followed by two weeks in Manhattan, New York. During this training, he learned about the other 11 or 12 competing products, the efficacy of Rebif, its safety and all about the reimbursement support services. As a Therapeutic Account Specialist, Harris and all the nurse educators mentioned in this Complaint were exposed to Defendants' unlawful scheme first-hand.

180. Harris explained that the nurse educators are third-party employees and that Serono hires these Consultants to essentially outsource and "manage that part of the sales force." Even though these nurse educators were employed by the Defendants, to the public, they held themselves out to be working for the Drug Companies. For instance, the nurse educators' business cards include EMD Serono's logo; not the third-party Consultants' logo.

181. In his personal practice, Harris spoke to Prescribers directly about Rebif's nurse educator services. When speaking to Prescribers, Harris would emphasize to them that "we offer nurse educator training" to ensure Prescribers' awareness of this service and to induce Prescribers to choose Rebif over competitor MS drugs.

182. Harris stressed the significant value that the nurse educators provided to the Drug Companies. To demonstrate the significant value of the nurse educators, Harris discussed how his own nurse educator contributed to his success with marketing and selling Rebif. He explained:

> my nurse educator has been in the market for 10 years. She would be introducing me [to doctors]. If doctors have any questions about patients, they can ask the nurse educator. She calls on offices just like me. She goes into doctors' offices and talks with medical assistants and nurses on her own. She has her own call route that includes seeing patients and doctors.

183. Once in contact with the Prescribers, Harris hosted a lunch for doctors. At these

lunches, Harris would invite the nurse educators to talk to the doctors and their staff. Harris explained that bringing the nurse educators to the lunches was a "double hit" for the Drug Companies because the nurse educators expanded Rebif's marketing reach to include not only Rebif's sales reps network of Prescribers but also the nurse educators' own network of Prescribers. In fact, he explained that "sometimes, [doctors'] offices don't see sales reps" at all because the nurse educator is the "touch point" with that Prescriber's office. The Prescriber offices' point of contact with the Drug Companies' Rebif team was indeed the nurse educators. The nurse educators were so involved that they could advise the doctors and the staff of a given patient's status.

184. Harris also described the "general disease awareness" programs held by nurse educators. Generally, disease awareness programs are offered to MS patients or caregivers who treat someone with MS. According to Harris, the Rebif nurse educators conducted these general disease awareness programs calling them "chat programs." The chat programs usually took place in the form of a lunch or dinner program. They were offered to any MS patient; not only Rebif patients. During these chat programs, the nurse educators discussed topics such as injection site reactions, tips, what happens with injectables, and side effects. More importantly, however, during these chat programs, the nurse educators highlighted the advantages of Rebif and how it is superior to other MS drugs/therapies. Specifically, the nurse educators discussed material and studies showing Rebif is superior to other medications in a head-to-head comparison.

185. Although these general disease awareness programs purported to provide patients with "general disease awareness," these programs really served as yet another marketing strategy for Defendants.

186. Beyond the day-to-day operations, Harris' team regularly held meetings which include salespeople, nurse educators, and medical science liaisons. Together, they re-grouped and

re-assessed their strategy. They discussed whether each nurse educator has done trainings for a certain doctor, and if not, Harris uses that as a starting point to talk with the doctor.

187. Mr. Harris worked "very closely" with the Rebif nurse educators to double Rebif's marketing and ultimately expand Rebif's reach to Prescribers' offices throughout the Atlanta, Georgia region. His nurse educator not only assisted in advertising Rebif to doctors and their staff at the lunch programs and to patients at the general disease awareness programs, but also informed him whenever Prescribers requested the nurse educator patient training through Rebif's MS LifeLines services and performed these at-home patient educator trainings.

188. Jean Powers was employed by Serono as a Key Account Manager promoting Rebif on contract and publicist from approximately February 2013 through October 2013 and then again February 2015 through March 2016. Her territory included Western Illinois and the Milwaukee, Wisconsin region.

189. Powers worked primarily with nurse educators. Specifically, she worked with field nurses and MS LifeLine nurses that answer the MS LifeLine program phones. She believes a majority of Rebif's nurses are contracted through Quintiles. In her territory, there was only one field nurse. Her observation was that Serono was trying to get nurses more involved in the office. For example, around 2016, Serono began pushing nurses to do more follow-up inversion calls with offices to report on a patient training, issues or success.

190. Powers explained that when pitching to offices, she and the other nurses were trained to emphasize Serono's MS LifeLines program and what it offers. They promoted that "no other company offers what they [Serono] do. It is a very comprehensive" service. Powers described that a physician need only send in a simple form to Serono. That form then goes to Serono's in-house reimbursement specialist located on the third-floor of Serono's Rockland,

Massachusetts headquarters so that the office "doesn't have to deal with it." Initial forms are partially pre-populated with the physicians' office information and other relevant points, so the Prescriber need only fill in the patient's name and check off a few boxes. MS LifeLines also employed nurse educators that can speak with patients 24 hours, seven days a week via an "800" number. Finally, MS LifeLines featured field nurses who provide one-on-one training with patients and conduct follow-ups. Whether this training takes place in the office or in the patient's home is up to the provider. Some providers wanted all of their patient education done in-house. In these situations, the field nurse trained the patient or instructed the provider's designee on how to train on Rebif. If, on the other hand the provider wanted the patient education to be done at the patient's house, the nurse educator conducted the patient training at the patient's home or wherever the patient preferred; the home was simply the rule of thumb.

191. Every office Powers called on was offered MS LifeLines. Powers explained that the doctors offered zero-dollar co-pay coupons and pap-based funding. She states that neither has an income limit and that the company would "do anything to get a patient on the drug." She mentioned that Serono recently benefited from the fact that Caremark removed Avonex (competitor MS drug/therapy) from its formulary list and replaced it with Rebif.

192. Powers explained that, beyond patient training, the field nurses provided patient education. Some of this education centered on the nurse asking the patient whether they knew the reason their doctor wanted them on Rebif. This helped confirm the patient's understanding of Rebif. This was also useful because the nurses reported it back to the sales reps, and the sales reps then reported back to the doctor advising the doctor that "what you [doctor] wanted out of the drug is exactly what is happening with the patient." What differentiated Rebif from other relapsing MS drugs/therapies was the support services that Rebif offered which competitor drugs did not,

especially the on-going nurse educator support services. Powers reiterated that patients valued nurse follow-ups at three months, six months and then every six months thereafter while on Rebif. For this reason, Rebif's field nurses promoted to doctors the points made by sales reps and emphasized that they continually provided patient support beyond initial patient training.

193. Powers believes that a Serono nurse educator's base salary is approximately $80,000 per year with a bonus opportunity of approximately $20,000. She was not aware of the metrics used to determine bonuses.

194. Nurse Educator Susan Wopperer was employed by Quintiles as a Rebif nurse educator from approximately 2012 to present. Her territory includes New York.

195. Wopperer described her training as one to two weeks of home study, mostly concerning MS. She also underwent "compliance and corporate" training, which ranged from HIIPA training to human resource issues. She then spent one week at Quintiles' headquarters learning reporting requirements and software use of Viva. Next, she traveled to Serono's headquarters in Rockland, Massachusetts for one week. There, she learned about Serono's reporting system because educators are required to enter data into both systems. Wopperer states that the Pharmaceutical Companies are currently working to remove this duplication of effort. Training at Serono also consisted of role-playing the office, meeting with decision-makers and overcoming objections. Susan found them "salesy" but states the skills Serono taught were useful in "selling what we do."

196. Wopperer's experience as a Rebif Nurse Educator mirrors that of Relators and the other nurse educators mentioned in this complaint, further confirming Defendants' unlawful schemes. According to Wopperer, Rebif nurse educators provide injection training and follow-up care to MS patients on Rebif. In addition to the initial injection training, nurse educators will visit

with Rebif patients approximately six times in the first year and then every six months thereafter. At these follow-up sessions, nurses check on everything from adherence to skin reactions and other side effects. Sometimes, nurses must retrain patients on injection methods if the patient's technique fails or if the patient begins using another of the three injection techniques. Occasionally, physicians request that she go see a patient concerning an issue, but for the most part patients seek care for issues from their physician. Notwithstanding the fact that patients cannot obtain Serono's MS LifeLines Services, such as the nurse education, until the physician prescribes Rebif, physicians have on occasion asked her to speak to a patient considering going on the medications to discuss how it works and what to expect.

197. Wopperer explained her personal practice and the significant value she provided to Prescribers and patients as a nurse educator. She stated she conducted an initial training for a patient starting Rebif. She would see the patient 5 to 6 times in the first year to make sure they are taking the medication and performing the injection properly. The patient also follows-up with their doctor twice a year and she assisted her patients in forming questions for the doctor. Prior to the injection follow-up with the doctor's office, Wopperer prepared a consultation report that can be scanned to the patient chart. The consultation report includes information such as: the last time the patient saw the doctor, the follow-up scheduled with the nurse, any bloodwork ordered, the type of device the patient is using, that the nurse made sure the medication is being stored correctly, rotation of the injection site, side effects, any barriers to adherence and the titration schedule. She informed that the patient consultation sheet is essentially a checklist for her during her meeting with the patient. Wopperer explained the fact that she reported patient trainings back to the doctor gave her an opportunity to bring up more "salesy type" discussions with the doctor.

198. Moreover, Wopperer organized and held "chat programs" once or twice a month.

Wopperer describes these "chat programs" as community programs providing a dinner or lunch. She held the chat programs in collaboration with the sales reps. The sales reps performed the sales aspect while she provides patient education. During the chat programs, they discussed MS general disease awareness and Rebif. Although the chat programs focused more on Rebif patients, if there was room left, they let other MS patients attend. The lunches usually draw 20 people and the dinners draw 20 to 30 people. Discussion topics included healthy living, getting support and motivation. With respect to Rebif as a topic, she discussed prescribing information, covered the different injection devices and methods of injection. She also discussed the support services provided by Serono's MS LifeLine Service. Wopperer disclosed that talking about Rebif is a requirement; she stated "[I] have to do that." When covering the different types of MS drugs, she discussed the clinical trials that showed Rebif to be superior to a competitor drug. Wopperer emphasized that the Drug Companies "absolutely" saw a benefit in terms of prescriptions; "that's why they fund the chat programs."

199. Wopperer emphasized that the Nurse Educator Programs help keep patients compliant which leads to physicians recommending Rebif over competitor MS drugs to his/her other patients which, in turn, results in increased Rebif sales. Wopperer concedes that this also helps the Drug companies, in the sense that it keeps the patient on Rebif. She believes that the "only reason" patients stay on the medication is because of the patient education. She demonstrates to patients how to manage side effects and remain adherent to the medication. Wopperer confirmed that her patient education services take the patient "off the doctor's plate," so to speak. She highlighted that because doctors generally do not have any type of program to ensure patient adherence, the Rebif nurse education services serve as a competitive advantage as it helps patients remain adherent and ultimately have better outcomes. Wopperer stated, "doctors love her service."

She recalls a nurse practitioner telling her once: "you are the *only* company that sees my patients and they are doing well." Because of this, the nurse practitioner continued to write prescriptions for Rebif.

200. Wopperer estimated that she educated patients 75% to 80% of her time, spending the remainder of her time performing "in-services" in doctors' offices. Wopperer's compensation included a salary and quarterly bonuses. Bonuses are tied directly to the number of patient visits and office visits she performs during the quarter, with different weights attached to each (or variations of each) depending on the quarter goals. She believes someone tracks the number of new starts but does not believe the numbers factored into her bonus.

201. Nurse Educator Bethany Boland (Boland) was employed by Quintiles as a Rebif nurse educator from approximately March 2011 to July 2012. Her territory included Connecticut and Massachusetts.

202. Boland identified Dr. Derek Smith as one Prescriber for whom she provided free patient management services beginning in 2011 through July 2012. During her tenure, Boland estimates that she and/or another Rebif nurse managed 90 percent of Dr. Smith's Rebif patients. She stated:

> I think that they were all offered the training, that was part of what I did in the office versus anybody else that didn't go in the office like the other contract people. A lot of patients [said] "well I don't need it, I did this before I got off and now I'm getting back on therapy." Something like that the doctor might not check this off so this is where from that training you can order them to have it and that's why it's only safe because even if they don't think they need it, check that box. But you know if we're identifying something that they don't know, they're probably going to want to come out as we talked to them on the phone.

203. In describing her experience with Dr. Smith, Boland stated that Dr. Smith provided her with positive feedback and acknowledged the significant time Boland spent educating his

patients:

> a patient you know they would call Dr. Smith, they didn't think that they needed to do it [training] and that they thought you told them something that helped them stay on the medication or walk them through the problem. So it's always something that they kind of get surprised when they hear the good feedback. They would get this feedback, the patients thought you were very helpful and spent a lot of time with them.

204. Another Prescriber Boland worked with was Physician's Assistant Stacey Panasci. Boland provided nurse educator services to Panasci's patients beginning in 2011 through July 2012. During her tenure, Boland estimates she and/or another Rebif nurse helped manage 90 percent of Panasci's Rebif patients.

205. In describing her experience with physician's assistant Panasci, Boland highlighted that most MS patients were provided with the nurse educator training, even if the patient believed they did not need it. She explained:

> I would say most of them you know about 90%. We always tried to get them to do it or just the biggest thing is getting the provider to order it on every patient even if the patient says "oh I don't need it." The provider getting them to say "listen I understand you don't think you need it but they say otherwise. Just rest assured, they spend a lot of time with you, they talk to you on the phone." So then you get them on the phone call and they say "yes okay right I did have a couple of questions."

206. Boland stopped providing nurse educator services in 2012 and became a pharmaceutical drug rep. Boland highlighted that even after leaving the Rebif nurse educator program to become a drug rep, she received preferential treatment when marketing drugs to these same Prescribers in later years. Boland stated that Prescribers such as Dr. Smith and PA Panasci recalled her as a Rebif nurse educator. Because of this, she had better access to these Prescribers' patients:

> I have better access than some other reps just because… so I would say even with Dr. Smith, like they remember me they remember that

> I'm not going to go get paid. I know that I have always taken care of their patients I would never want anything to happen to the patient so anything I do is always about the patient, and they remember that you know.

207. Nurse educator Karen Campione (Campione) was employed by RXC as an overflow Rebif nurse educator from 2013 to the present. As an overflow Rebif nurse educator, Campione took on patients whenever other Rebif nurse educators were too busy to take on additional patients. Her territory included south-eastern Pennsylvania and southern New Jersey.

208. Campione identified numerous Prescribers for whom she provided free patient management services throughout Pennsylvania and New Jersey: Dr. Syed Jaffery; Dr. Thomas Mirsen; Dr. Manzoor Abidi; Dr. Ravi Dukkipati; Dr. Thomas Leist; and, Dr. Dina Jacobs.

209. Nurse educator Lauran Donofrio (Donofrio) was employed by RXC as an overflow Rebif nurse educator beginning in 2014 to the present. Her territory included the state of Florida.

210. As an overflow Rebif nurse educator, Donofrio assisted full time Rebif nurses when they were too busy to make home visits or follow-up with the patient:

> They get the referral…they have to contact me with the information, and send it to me, and when their nurses are too busy because they're full-time nurse can't get over there, they just make the call. They are required to do it [make contact with the patient] within 24 hours of getting the referral.

211. Nurse educator Tracie Sloui (Sloui) was employed as a Rebif nurse educator by Quintiles from 2009 to 2013 and employed by RXC from October 2013 to July 2014. Her territory included Syracuse and Albany, New York and the surrounding area.

212. Sloui identified several key New York Prescribers for whom she provided free patient management services throughout the Albany and Syracuse region: Nurse Practitioner Jeanne Ceballos; Dr. Keith Edwards; Dr. Burk Jubelt; and, Dr. Hassan Shukri-Mahmod.

213. Although Sloui did not personally manage all of these Prescribers' patients, Sloui

confirmed that most if not all of the Prescribers' patients received some form of free nurse services because "it was very rare for Rebif to be started without nurse educator training."

214. Sloui disclosed that immediately upon completing training and being assigned to a region, the nurse educators' goal was to "meet [all the doctors] as soon as possible" and begin to offer to provide free nurse services for their patients. In her personal experience, "September was when [she] started training, and then October, November, [and] December it was focused on meeting all the doc[tors] including with [her drug] rep because [she] had Albany and Syracuse."

215. Once a Rebif nurse educator, such as herself, was introduced to the doctor, the doctor became more likely to write more Rebif prescriptions "because they trust you. They know you take care of their patients. We gave better care at the patient's home than the doctor could give at the office. We were needed by the doctors."

216. Nurse educator Barbara Van Asdian (Van Asdian) was employed by Quintiles as a Rebif nurse educator from 2007 to September 2013. Her territory included Salt Lake City, Utah and the surrounding area.

217. Van Asdian's practice involved first obtaining a list of doctors in the Salt Lake City region from drug reps as well as the drug reps' calendar to determine on which days the drug reps set up lunches and education meetings with the doctors and patients. Van Asdian would then attend these lunches with the drug reps to meet with doctors and patients to provide the nurse educator training on Rebif. Once there, Van Asdian would immediately meet with the patients to conduct the initial training either before or after the lunch. Van Asdian also provided doctors and patients with her direct contact information and offered to answer any questions that the doctors and patients may have afterwards.

218. In addition to the initial patient training, Van Asdian also conducted follow-up

education training to these patients whenever necessary. Overall, the doctors provided positive feedback to her based on their patient's experience with the nurse educator training.

219. Van Asdian identified several key Utah Prescribers for whom she provided free patient management services throughout the Salt Lake City region: Dr. Jeffrey Groves; Nurse Practitioner Julia Klein; Dr. Denise Skuster; Dr. John Rose; and, Dr. Joseph Watkins.

220. The Rebif free nurse educator program involved patient training on all aspects of the drug, including demonstrating injections, discussing symptoms and side effects and answering any questions the patient may have about Rebif. Van Asdian explained:

> I would demonstrate to them how to do the injection, and I would go over everything, the symptoms and everything. I would tell them that they did very well, and [the doctor] knew I would go out to see them if they needed me to go out, and we did two months follow up visits anyway. I would – I made myself available to them.

221. During his tenure, Relator Harris worked with two Rebif nurses. Nurse Sheila Birch with whom he worked for most of his time and nurse Patrice Harris (no relation) with whom he worked the last part of this tenure. In the manner set out above, these two nurses provided free nurse services to the following Prescribers: Dr. Mitzi Williams; Dr. Jeffrey English; and Dr. Robert Gilbert from the MS Center in Atlanta; Dr. Ben Thrower, Dr. Cheryl Lorring and Dr. Guy Buckle of the Sheppard Center; and Dr. Reinaldo Verson of the Columbus MS Center.

222. Given that the nurse educators were performing medical services that the Prescribers or their staff would otherwise have been required to perform, Defendants' free nurse educator program unequivocally provided Prescribers with substantial independent value. The Rebif free nurse educator services relieved Prescribers of their duty to educate and monitor patients on Rebif and shifted the administrative burden of educating and monitoring the patient utilizing Rebif to Defendants. The countless hours these nurse educators expended training, educating and

monitoring Rebif patients saved Prescribers a significant amount of resources and money. The time and labor that the Rebif nurse educators expended in educating and monitoring the Prescribers' patients ultimately translated into significant savings of the Prescribers' and their staffs' own time and labor required to manage MS patients. The value to Prescribers is also captured by the sheer number of Prescribers who utilized or are utilizing nurse educator services. Van Asdian estimated that 90% of Prescribers who prescribed Rebif also utilized the free nurse educator services.

223. The substantial value that the free nurse educator services conferred upon Rebif Prescribers was also independent of the drug itself because but-for the free nurse educators provided by Serono and Pfizer in partnership with Quintiles and RXC, Prescribers would have had to hire their own third-party nurse educators or utilize their own time, labor and resources to educate and monitor their MS Patients. The free nurse educator services furnished independent value to Prescribers because the free nurse educator services provided by the Drug Companies and Consultants eliminated an expense that the Prescribers would have otherwise incurred.

224. By offering the Rebif free nurse educator services in tandem with the drug, the Drug Companies provided a service that conferred substantial independent value to Prescribers.

225. Because the Rebif free nurse educator services conferred substantial independent value to Prescribers, it amounted to illegal remuneration in violation of the AKS.

226. All of these nurse educator services would have been a cost to the Prescribers if not for the Drug Companies providing the Nurse Educators to the Prescribers free of charge. Thus, the Drug Companies were materially decreasing the Prescribers' cost of treating MS patients, and correspondingly increasing their own profits as well as the profits of the Prescribers.

227. Of course, in typical quid pro quo fashion, in order to be given these free nurse

educator services, those Prescribers would have to "support" (i.e., write prescriptions for) the Drug Companies' MS drugs.

228. Once trained and deployed, the Nurse Educators began to provide free education services to any Prescriber who would prescribe the Drug Companies' products. The Consultants' Nurse Educators were successful in saving Prescribers time, money and resources and, in many instances, resulted in receiving higher reimbursement rates associated with certain MS care metrics. Not surprisingly, the Drug Companies also saw its drug sales increase each time a Nurse Educator was deployed.

229. In sum, the Free Nurse scheme reduced the time and cost required of Prescribers across the nation to treat chronically ill MS patients taking Rebif, thereby freeing up Prescribers' and their staff's time and resources. These services permitted Prescribers to take on additional patients and increase their E/M volume, thereby increasing the overall profitability of their practice.

230. In the manner described above, Serono and Pfizer, with the assistance of Quintiles and RXC, enabled Prescribers to "eliminate an expense that [they] would have otherwise incurred"[40] if they had directly employed the Rebif nurses or provided the services themselves.

231. The Nurse Educators provide a substantial independent value to Prescribers because they save Prescribers significant time and resources for which the Prescribers would

[40] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Dep't of Health & Human Servs*., 68 Fed. Reg. 23731-01, 23737 (May 5, 2003), *available at* https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf (concluding that "**if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician)**, or if items or services are sold to a physician at less than their fair market value, **the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer**. Moreover, under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business)(emphasis added)).

otherwise be paying to help professionally manage the wellness of patients under the Prescriber's care.

232. The fees Serono and Pfizer paid to implement the Free Nurse Educator program underscores the substantial value these nurse services provided to Prescribers.

233. The tasks performed by the Serono/Pfizer and RXC/Quintiles nurse educators encompass medical care that the Prescribers were otherwise duty-bound to deliver to patients that had been prescribed Rebif. But-for Serono and Pfizer agreeing to underwrite this work, Prescribers would have had to either hire staff or outsource the nurse services and would have had to pay fees like those paid by Serono and Pfizer to RXC and Quintiles.

234. Even if Prescribers did not hire additional staff or outsource the nurse services, Prescribers would have had to redirect their existing nursing staff to devote significant time and effort to perform these tasks. This would result in a loss of productivity elsewhere by existing nursing staff, which Prescribers would ultimately bear.

235. Defendants identified this opportunity cost to Prescribers and specifically used it as a mechanism for luring Prescribers to contract with Defendants to hire the Rebif Nurse Educators. These Nurse Educators provided substantial independent value to Prescribers in the form of a time savings.

236. The free nurses are effectively free employees given to Prescribers at *no* charge, in exchange for the Prescribers' commitment to recommend and prescribe Rebif products to their patients over competing MS drugs.

237. This conduct violates the federal Anti-Kickback Statute because it provides remuneration in the form of free nurse services to induce Prescribers to prescribe a drug or service, resulting in the submission of false claims to Medicare, Medicaid, TRICARE and other Federal

Healthcare Programs.[41] Prescribers are induced and incentivized to prescribe Rebif because of the substantial benefit they receive in exchange for prescribing Rebif from the free Nurse Educator services. By providing the Nurse Educator services to healthcare providers in exchange for Rebif prescriptions to be reimbursed by the Federal Healthcare Programs, the Defendants violated the AKS.

The Individuals Involved in the Free Nurse Educator Scheme

238. The Free Nurse scheme was designed and developed by Serono and Pfizer, with administrative input and guidance by Quintiles and RXC.

239. Numerous Serono, Pfizer, RXC and Quintiles employees have been involved in developing and administering the Free Nurse Program:

Name	Employer	Title/Dates of Employment	Role
Alexandra Simon	Serono	Associate Director, Devices Neurology and Immunology: 08/2015 – 12/2016 Associate Director, Rebif Strategic Marketing: 01/2017 – 12/2017 Director, Head of Business Liaison: 01/2018 – present	Helped develop, oversee and administer the Free Nurse Educator Program for Rebif.

[41] *See, supra*, note 38. There is ample scientific research demonstrating the that remuneration from pharmaceutical companies are associated with more prescriptions per patient, more costly prescriptions, and a higher proportion of branded prescriptions with variation across specialties. "Gifts of any size had an effect and larger gifts elicited a larger impact on prescribing behaviors." *See* Wood SF, Podrasky J, McMonagle MA, Raveendran J, Bysshe T, Hogenmiller A, et al. (2017) *Influence of pharmaceutical marketing on Medicare prescriptions in the District of Columbia*, PLoS ONE 12(10): e0186060, *available at* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0186060 (last accessed Nov. 20, 2018). While large gifts are a more visible examples of commercial influence, there is also ample evidence that even small remuneration can be influential on Prescribers. In fact, this phenomenon is precisely the reason why Congress and the States have enacted and strengthened the AKS.

Name	Employer	Title/Dates of Employment	Role
Angel Powers	Serono	Marketing Support, Rebif Brand Team: 2010 – 2014 Marketing Coordinator, Rebif Marketing: 2014-2016 Associate Product Manager, Rebif Consumer Marketing: 2016 – present	Managed Rebif marketing focused on patient/consumer awareness, acquisition and adherence.
Bill Dooley	Serono	Principal Clinical Operations Lead: 05/2013 – present	Oversaw the administration of the Rebif Nurse Educator operations.
Drew Young	Serono	Senior Vice President, US Neurology and Immunology: 06/2014 - 08/2016 Vice President, Global Neurology: 07/2018 to present	Developed strategic direction for Rebif with co-promoter Pfizer in 2014-2015 to increase Rebif sales by developing various Rebif programs, including the free Nurse Educator Program.
Eric McCrory	Serono	Key Account Manager, Area Field Trainer: 06/2015 – present	Promoted Rebif to targeted Prescribers and implemented Rebif's patient education program, including the Nurse Educator Program.
Greg Mylander	Serono	Key Account Manager: 09/2006 – 03/2010 Area Business Director: 04/2010 – present	Managed the Free Nurse Educator Program to Prescribers and coached sales team on how to grow Rebif's market share.
Jennifer Krainman	Serono	Key Account Manager, Neurology (MS): 11/2011 – 08/2016 Product Manager, Marketing: 09/2016 – 04/2018 Senior Product manager, Marketing: 04/2018 – present	Facilitated Prescriber sponsor events and patient Nurse Educator Programs geared towards promoting Rebif in New York region with focus on MS management.

Name	Employer	Title/Dates of Employment	Role
Lindsay Harrer	Serono	Thought Leader Liaison: 11/2014 – 05/2016 Area Business Director: 05/2016 – present	Implemented and managed sales and marketing tactics for Rebif with sales representatives and nurse educators to increase sales in New York and New Jersey.
Michael Calabro	Serono	Thought Leader Liaison: 10/2010 – present	Coordinated Rebif field representatives, including Nurse Educators and Reimbursement Support Services in New Jersey, Pennsylvania, Delaware and Ohio.
Michael Lucy	Serono	Regional Account Manager: 02/2010 – 11/2014 Northeast US Area Business Director, Neurology & Immunology: 11/2014 – present	Oversaw coordination of various Rebif Nurse Educators and Reimbursement Support Services throughout Northeast US.
Scott Holiday	Serono	Area Business Director, Neurology: 06/2015 – present	Managed coordination of Field Nurse Educators and Reimbursement Support Services to increase Rebif sales.
Celeste Foster	RXC	Nurse Educator: 02/2013 – 10/2015	Provided Rebif patient education services in Kentucky, including traveling to patient homes, teaching proper self-injection techniques and providing education regarding the drug.
Christopher Faber	RXC	Case Manager, Human Resource Trainer, Supervisor: 03/2015 – present	Trained field Nurse Educator new hires.

Name	Employer	Title/Dates of Employment	Role
Grant Compton	RXC	Director, Specialty brand Support Operations: 2014 – present	Oversees client service programs, including Reimbursement Support Services and Nurse Educator Program in Kentucky.
Steve Lynch	RXC	Vice President of Business Development: 01/2016 - present	Organizes with Serono/Pfizer to create and develop Rebif marketing strategies including through Field Nurse Educators Program and Reimbursement Support Services in Florida.

240. Relator's investigation reveals that, to retain and implement the services of Nurse Educators, Serono and Pfizer paid millions of dollars each year.

241. The above mentioned individuals played significant roles in designing, developing and implementing the unlawful Free Nurse Educator scheme with the singular goals of increasing Rebif prescriptions and sales.

The Duration of the Free Nurse Educator Scheme

242. Relator's investigation establishes that Quintiles and RXC have administered the Rebif Free Nurse Program since at least 2006. The Free Nurse programs were viewed by Serono and Pfizer as a key part of its efforts to drive Rebif prescriptions and sales and, accordingly, have been administered continuously once established for Rebif.

243. For instance, Drew Young (Young) worked for Serono as Senior Vice President from June 2014 through August 2016 in the Boston, Massachusetts area. During that time-frame, Young developed strategic direction for Rebif in collaboration with Pfizer with the goal of increasing Rebif sales. As part of the Drug Companies' strategic plan for Rebif, he assisted in

developing and marketing to Prescribers the field Nurse Educator program.

244. In another example, Eric McCrory (McCrory) worked for Serono as a Key Account Manager from June 2015 through present. McCrory engaged in similar strategic planning initiatives throughout Texas.

245. According to Nurse Wopperer, Quintiles and Sereno have contracted for Rebif nurse educators since approximately 2006 – and that the companies recently renewed the contract for three more years. Her understanding is that this is among the longest third-party contracts in the pharmaceutical industry.

246. Through Relator's investigation, Relator has learned that the Drug Companies, including Serono and Pfizer enter into detailed contracts with vendors such as the co-Defendant vendors. These contracts are re-negotiated based upon the drug companies' "ROI" or return on investment of drug sales from the payments it makes to the co-Defendant vendors. Those contracts include an attached Scopes of Work, referred to as "SOWs." The SOW for Serono and Pfizer's Contract spells out in detail each discrete task that is to be performed and the payment that will be made for each. These contracts are not publicly available but are in the exclusive possession and control of the Defendants and will spell out the precise dates that the scheme began.

The Geographic Span of the Free Nurse Educator Scheme

247. The Free Nurse Educator program is administered nationwide and is available to patients throughout the United States.

248. Relator's investigation reveals that the Free Nurse program has been implemented in every region of the United States and in almost all 50 states.

C. THIRD SCHEME: QUID PRO QUO KICKBACKS – FREE REIMBURSEMENT SUPPORT SERVICES IN EXCHANGE FOR REFERRALS

The Background of the Unlawful "Reimbursement Support Services" Scheme

249. In its third scheme, the "*Reimbursement Support Services*" Scheme, Serono and Pfizer induced Prescribers to recommend Rebif by offering and providing Reimbursement Support Services to Prescribers who wrote Rebif prescriptions.

250. Relator Harris explained that, generally, when a Prescriber writes a prescription for Rebif, a number of additional administrative tasks must be completed before the patient is able to "fill" the prescription at the pharmacy. These tasks customarily include:

- Determining whether and to what extent the patient has prescription drug insurance benefits;
- Determining if the drug is on the formulary lists and, if so, the applicable tiers;
- Seeking a coverage determination for the drug from the patient's carrier[42];
- Determining the patient's co-pays and deductibles;
- Determining whether a patient may qualify for "co-pay" assistance or coupons;
- Appealing any denial of coverage or prior-authorization;
- Determining the in-network pharmacy where the patient can have the drug filled;
- Communicating this information to the patient; and,

[42] In cases of Medicare and Medicaid, this is called a "coverage determination." For Medicare patients, a coverage determination is particularly cumbersome and time consuming given the complexity of many Part D plans, which have four coverage phases: (1) a "deductible" phase, where a patient pays 100% for drug costs until the deductible amount is met; (2) an "initial coverage" phase, where a patient pays a percentage of the drug cost depending on the carrier and the drug's formulary position; (3) a "coverage gap" or "donut hole" phase, where, as of 2017, a patient pays 40% of the cost for brand-name drugs and 51% of the cost for generic drugs; and (4) a "catastrophic coverage" phase, where, as of 2017, a patient pays either 5% of the covered drug cost or $3.30 for generics and $8.25 for brand name drugs. *See, e.g.*, *Humana Part D 2017 Plan Year Stages*, *available at* https://www.humana.com/medicare/products-andservices/drug-plan/medicare-part-d-stages.

- Managing the resultant paper trail.

251. Relator's industry research revealed that as part of managing a patient's care, it is the Prescriber's responsibility to complete the numerous administrative steps between writing a prescription and the patient's receipt of the drug. These steps are time-consuming, averaging roughly 20 hours per week for a Prescriber's office.[43] Because completing these tasks requires the attention of the Prescriber and his or her staff, each task bears discrete economic costs to the Prescriber.

252. For certain prescription drugs that are particularly expensive, like Rebif, a Prescriber's staff must also work with the patient's insurance carrier to obtain what is known as a "prior authorization." A prior authorization is the requirement that a Prescriber obtain approval from the patient's health insurance plan before the drug can be dispensed by a pharmacy – or the patient may be required to pay for the medicine "out of pocket."

253. Because it entails advocacy on behalf of the patient, obtaining prior authorization is a responsibility that falls within the Prescriber's duty of care.[44] Importantly, numerous states have enacted legislation that requires Prescribers to obtain prior authorizations on behalf of the patients.[45]

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[43] See Christopher P. Morley, David J. Badolato, John Hickner, and John W. Epling, *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, J. Am. Board Fam. Med. (January-February 2013), Vol. 26 no. 1, at 93-95.

[44] *See Getting Medical Pre-approval or Prior Authorization*, *available at* https://www.cancer.org/treatment/finding-and-paying-for-treatment/understanding-healthinsurance/managing-your-health-insurance/getting-medical-pre-approval-or-priorauthorization.html (noting that "Prior authorization is often used with expensive prescription drugs. It means that your doctor must explain that the drug is medically necessary before the insurance company will cover it. The company may want you to use a different medicine or try a different one before they will approve the one your doctor prescribes.").

[45] *See, e.g.*, Ala. Medicaid Preferred Drug and Prior Authorization Program, Prior Authorization Criteria Instructions; Cal. Health and Safety Code, § 1367.241; 10 CCR 2505-10, § 8.017E; Delaware Health and Social Services General Policy, § 1.17; Florida Medicaid, Authorization Requirements Policy, §2-2.4.4 (June 2016); Georgia Dept. of Comm. Health Medicaid Fee-for-Service Pharmacy Prior Authorization Request Process Guide; Louisiana Medicaid Program Provider Manual, Chapter 37, § 37.5.5; Mass. Health Provider Manual, § 450.303; Mich. Dept. of Health and Human Servs., § 7.5; Minn. Statutes, § 62J.497, subd. 5; NY State Medicaid Program, Physician Prior Approval Guidelines; N.C. Dept. of Health and Human Servs., Prior Approval and Due Process;

254. Further, large Managed Care Organizations, which administer the Medicaid programs in several states and Medicare Advantage plans throughout the country, also specifically require Prescribers to perform prior authorization services for the drugs they prescribe.[46]

255. Federal Healthcare Programs such as Medicare, Medicaid and TRICARE also require the prior authorization process to contain costs associated with expensive medications. This is particularly true for products like Rebif, which are expensive and come with a myriad of potential side effects that may require other medications to manage. For such products, carriers routinely require Prescribers to "make a case" of medical necessity and explain why a less expensive product is not an acceptable alternative.[47] This process is designed to save taxpayer dollars by ensuring that the more expensive medications are prescribed only when needed.

256. As a coalition of healthcare organizations led by the American Medical Association has recognized, coverage determinations, prior authorization, and appeals often entail "very manual, time-consuming processes . . . [that can] divert valuable and scarce resources away from

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NJAC 10:51-1.14; Oregon Health Authority, Instructions for Submitting Prior Authorization Requests for Oregon Medicaid Providers (Aug. 2015); Pennsylvania Pharmacy Prior Authorization General Requirements; S.C. DHHS, Pharmacy Services Medicaid Provider Manual, § 2; Tenn. Medicaid Pharmacy Claims Submission Manual, § 7.6; Texas Admin. Code. Title 28, § 19.1820; Texas Admin. Code. Title 1 § 531.073; WV Health and Human Resources Bureau Manual, § 518.2.

[46] *See, e.g.*, *Molina Medicaid New Mexico 2014 Provider Manual*, § 6; *see also* Anthem BlueCross BlueShield, *Preauthorization requirements*, *available at* https://www.anthem.com/wps/portal/ahpfooter?content_path=shared/noapplication/f2/s3/t0/pw_006531.htm&state=co&label=Preauthorization (noting that "[t]he physician who . . . orders the procedure or service is responsible for obtaining preauthorization"); *Michael Bilhari, M.D., Insurance Companies Use Prior Authorization to Keep Health Care Costs in Check* (Jan. 21, 2017), *available at* https://www.verywell.com/prior-authorization-1738770 ("Prior authorization is a requirement that your physician obtain approval from your health care provider before prescribing a specific medication for you or to performing a particular operation. Without this prior approval, your health insurance provider may not provide coverage, or pay for, your medication or operation, leaving you to cover some, or all, of the costs out of pocket.").

[47] *See, e.g.*, *Exceptions and Appeals for Drug Therapies: A Guide for Healthcare Providers*, *available at* https://www.janssencarepath.com/sites/www.janssencarepath.com/files/ exceptions-and-appeals-for-drug-therapies.pdf ("Prior authorization (PA) processes require healthcare providers to contact and receive approval from a patient's payer before that payer will cover a certain prescription drug. In these situations the prescriber must substantiate-verbally or in writing-why a particular therapy is medically necessary."). S*ee also Prior Authorizations: A Payer's Perspective*, Medical Economics (July 8, 2014), *available at* http://www.medicaleconomics.com/modern-medicine-feature-articles/prior-authorizationspayers-perspective.

direct patient care."[48] Further, industry research demonstrates that these tasks are time-consuming and costly for Prescribers. For instance, a study of 12 primary care practices published in 2013 in *The Journal of the American Board of Family Medicine* concluded that "preauthorization is a measurable burden on physician and staff time."[49]

257. According to another study published in 2009 in Health Affairs, primary care Prescribers spent a mean of 1.1 hours per week on authorization-related work, primary care nursing staff spent 13.1 hours, and primary care clerical staff spent 5.6 hours.[50] The same study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually.

258. Alternatively, if a Prescriber does not wish to pay its own staff to carry out these administrative tasks, Prescribers can outsource them to third-party commercial vendors for a fee. Numerous vendors provide such outsourcing services. A study conducted by Deloitte on behalf of a large pharmaceutical company demonstrates that medical practices pay up to $98 for initial insurance verification, up to $75 for insurance re-verification, up to $111.82 for prior authorizations, and other à la carte fees:

[48] *See Prior Authorization and Utilization Management Reform Principles*, *available at* https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-forslsc.pdf.
[49] *See Morley*, *supra*, note 42, at 93.
[50] *See id.* at 95 (*citing* Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra, Theodore Karrison, Wendy Levinson, *What Does It Cost Physician Practices To Interact With Health Insurance Plans?*, *Health Affairs* (July-August 2009), Vol. 28 no. 4, at 533-43).

Activities	Lash	McKesson	Covance	Incumbent Average
Re-verfication	$20.75	$75.00	$50.00	$41.53
Insurance Verification	$98.00	$75.00	$75.00	$88.50
Reimbursement Support - Rate Verification	$68.00	$65.00	$0.00	$62.52
Coding & Reimbursement Assistance	$20.75	$30.00	$12.45	$23.43
Claims Support and Appeals	$104.28	$125.00	$57.78	$108.45
Ad Hoc Support and Consulting	$100.00	$100.00	$1.00	$93.54
Co-Pay Card Program Administration	$1.00	$0.00	$1.00	$0.65
Field Reimbursement Services	$19,180.00	$10,000.00	$1.00	$14,736.15
Site Visit/ Telecon	$2,150.00	$100.00	$1.00	$1,296.80
General Inquiry	$20.75	$15.00	$12.45	$18.21
Injection Network and Location Support	$104.28	$30.00	$12.45	$72.45
Sales Portal	$5,000.00	$100.00	$45,000.00	$5,904.35
Provider Portal	$8,000.00	$2.50	$0.00	$4,696.52
Plan Comparison	$20.75	$125.00	$88.65	$61.44
Send Hotline Material	$0.60	$15.00	$12.45	$6.38
Benefit Summary Call	$0.00	$100.00	$0.00	$34.78
PAP Prescreening and Referrals	$62.00	$30.00	$89.65	$52.67
Prescription Triage	$68.00	$100.00	$12.45	$75.51
Prior Authorization	$68.00	$75.00	$111.82	$73.29
Injection Reminder	$21.00	$15.00	$12.45	$18.36
Analytics and Reporting	$110.00	$100.00	$135.00	$108.15
Sales Rep Hotline	$20.75	$15.00	$12.45	$18.21
Sample/Vouchers	$100.00	$30.00	$12.45	$69.94
CSR Training and On-boarding	$0.00	$100.00	$0.00	$34.78
Language Line	$0.00	$100.00	$1.00	$34.85
Telecommunications	$0.40	$100.00	$1.00	$35.08

259. Regardless of whether these administrative tasks are outsourced to third parties or performed in-house, the tasks that must be completed before prescriptions are filled result in significant, tangible administrative costs to Prescribers. These are direct costs that Prescribers would have to incur to perform or outsource the burdensome administrative tasks associated with Support Services.

260. Despite the significant administrative costs associated with providing Support Services, Prescribers are not permitted to charge the patient or their insurance provider for

performing such tasks.[51] Prescribers must either assign their own staff to perform these tasks or outsource the work to a third-party vendor. Thus, when an office-based Prescriber receives payment for an office consultation,[52] the payment is intended to compensate the Prescriber for both the medical care given *and* administrative tasks associated with that patient's care.[53] These tasks necessarily include Support Services.[54]

261. Because a provider's reimbursement for each office visit is fixed per unit, Prescribers are continuously seeking ways to combat and reduce overhead costs and expenses in order to earn more profit from each E/M unit billed. One way to reduce these costs is to lessen the administrative costs associated with prescribing MS drugs. If a Prescriber can reduce or eliminate this cost, each E/M unit will be more profitable, and their staff will have more time to devote elsewhere.

262. Given that the administrative tasks associated with the provision of Support Services are time-consuming and tedious, these economic considerations directly impact a Prescriber's prescribing behavior. Prescribers are less likely to prescribe a drug that imposes an

[51] For example, in Texas, "[p]roviders must certify that no charges beyond reimbursement paid under Texas Medicaid for covered services have been, or will be, billed to an eligible client." The Texas Medicaid Provider Procedures Manual makes clear to providers that "Federal regulations prohibit providers from charging clients a fee for completing or filing Medicaid claim forms" and notes that the "cost of claims filing is part of the usual and customary rate for doing business." Further, providers cannot charge "Texas Medicaid clients, their family, or the nursing facility for telephone calls, telephone consultations, or signing forms." *Texas Medicaid Provider Procedures Manual* § 1.6.9 (Dec. 2017), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx (last accessed, Dec. 20, 2017).

[52] The technical term for an office visit is "evaluation and management services" or "E/M." In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. Medicare pays over $11 billion each year for E/M services alone. Medicaid and private insurers also pay billions each year.

[53] For example, if a provider receives $50 for an E/M service, a portion of that $50 is intended to compensate the provider for the administrative tasks inherent in managing that patient's care.

[54] To reiterate, these administrative tasks include: determining the patients' prescription drug insurance benefit verifications, determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles and telephone calls to patients, responding to patient complaints, returning messages and faxes, handling prescription refill requests and, where necessary, obtaining prior authorizations, and handling the resulting paper trail.

undue burden on support staff because doing so consumes the staff's time and limits the number of patients that can be seen in a day, thereby, decreasing profitability. Conversely, a Prescriber is much more likely to prescribe a drug if it can be prescribed with little or no administrative burden because doing so frees up staff and allows more patients to be seen in a day, thereby, increasing profitability. Thus, the Prescriber's relative cost and burden in prescribing one pharmaceutical company's drug when compared to another pharmaceutical company's drug can directly influence which drug a Prescriber will recommend and ultimately prescribe to a patient.

263. According to Relator, these factors were not lost on Serono and Pfizer. Indeed, Serono and Pfizer readily assumed the expense the Prescribers would otherwise have had to incur, knowing that the availability of Support Services served as a powerful inducement to Prescribers to recommend Rebif over a competitor's drug.

264. With expensive MS drugs, such as Rebif, the "hoops" a Prescriber must jump through to obtain a prior authorization for coverage can be very time-consuming and arduous process for Prescriber, and the Drug Companies are fully aware of this challenge. Thus, to increase prescriptions for Rebif, Serono and Pfizer developed a concierge of Rebif Support Services that are marketed to Prescribers in tandem with marketing Rebif to increase the likelihood that Prescribers choose to recommend Rebif over other products.

265. The Reimbursement Support Services provided by Serono and Pfizer were comprehensive and intended to provide a material advantage to the physicians choosing Rebif over competing drugs, some of which required less paperwork to authorize with insurance companies or other payors.

266. When pitching Rebif to Prescribers, Relator Harris and the Drugs Companies' sales reps emphasized that, if the Prescriber prescribed Rebif, Serono and Pfizer would provide – free

of charge – the services and resources of a full reimbursement support team to manage the administrative tasks associated with prescribing the drug. Rebif sales reps emphasized that the cost and expenses normally associated with managing a patient's prescription would be shifted to the Drug Companies, thereby, increasing the Prescriber's bottom line. The drug reps could offer a provider an "on call" reimbursement support team to manage patients' drug prescriptions. Support Services very much became a key component of the Serono drug reps' collective sales pitch because it was a way of offering physicians increased profitability.

267. This value proposition proved a powerful tool in the hands of Serono and Pfizer's nurse educators and drug reps and served to influence Prescribers to recommend Rebif. In short, offering the free Reimbursement Support Services as a complementary service automatically provided with Rebif prescriptions served as a way of inducing and compensating Prescribers to prescribe Rebif.

268. Serono highlights the role of their "Financial Support Specialists"[55] in providing reimbursement services to patients:

> Our trained Financial Support Team members at MS LifeLines can also assist you with the following:
>
> - **Submitting forms to determine eligibility** for financial assistance programs
> - **Coordinating with pharmacies to fill your prescription** in a timely manner
> - **Understanding your Medicare prescription drug coverage for the cost of your Rebif**
> - Exploring your financial options and patient assistance programs
>
> Though we cannot guarantee that you will receive coverage or reimbursement for your therapy, our team will focus on conducting a thorough review of your situation to determine eligibility for an

[55] Serono refers to their MS LifeLines team that provides Reimbursement Support Services as "Financial Support Specialists." *See* Rebif, *One-on-One support, available at* https://www.rebif.com/rebif-one-on-one-support/rebif-financial-services (last accessed Dec. 8, 2018).

> MS LifeLines assistance program. Or, **we will refer you to the appropriate state or federal program**.[56]
> (emphasis added)

269. Relator Harris explained that Rebif is administered by a specialty pharmacy. Harris also explained that often, he spoke directly with a doctor's nurses and not the doctor as the doctor already knows about Rebif since it is a decade-old drug. In speaking with a doctor's nurses, he asked the nurses to send the patient information to the reimbursement specialists so they can get Rebif covered for that particular patient.

270. Harris explained that patients can get "free product" for up to one year. The patient qualifies for free Rebif if the patient was denied for reimbursement by their insurance, but they were otherwise still a good candidate for the product. He also explained if the patient loses their job, Serono would not take the patient off the Rebif therapy. Instead, Serono would give the patient free product for at least one year. Providing a patient with free product when their insurance denies reimbursement or when the patient loses their job ensured that the patient remained on Rebif therapy while the Reimbursement Support Services took up an appeal on behalf of the patient to re-obtain coverage for Rebif. The MS LifeLines Reimbursement Support Services "took care of all of that."

271. Harris explained that once a patient goes through the process of reimbursement assistance, nurse education, and using Rebif, the patient became a guaranteed Rebif patient. Once he has secured a certain patient as a Rebif patient, Harris returned to the doctor and asked: "do you have anyone else that fits that bill?"

272. MS LifeLines differentiates Rebif from other MS drugs/therapies. The doctors that Harris worked with regularly told him "your customer service and reimbursement line is top-

[56] *Id.*

notch."

273. By engaging in this unlawful practice all across the country and with hundreds or thousands of Prescribers, the Rebif patient list grew and Rebif sales grew as a result over the last decade in which Defendants have carried on these unlawful schemes.

274. Relator Harris identified Dr. Mitzi Williams; Dr. Jeffrey English; and Dr. Robert Gilbert from the MS Center in Atlanta; Dr. Ben Thrower, Dr. Cheryl Lorring and Guy Buckle of the Sheppard Center; and Dr. Reinaldo Verson of the Columbus MS Center as providers to whom he targeted and who received free reimbursement support services in the manner identified above.

275. John McCann was employed by Serono as a Case Reimbursement Specialist from approximately March 2016.

276. McCann believed that Rebif's sales reps gathered more "buy-ins" from Prescribers because of Rebif's Reimbursement Support Services. He explained that doctors are generally apprehensive to new products unless they have staff that can handle reimbursement support services in-house. Because of this, sales reps promoted the service to Prescribers and offered a flyer advertising the service as well.

277. McCann performed benefit verifications for Rebif. McCann estimated that benefit verifications take 20 minutes to an hour and a half. This is time and expense that the Prescriber's office would otherwise have to incur. As part of his day-to-day activities, McCann made direct calls to insurance companies to verify benefits. He then prepared a report and faxed the report back to the provider's office.

278. McCann also performed benefit verifications online. When conducting benefit verifications with insurance companies and government programs, Mr. McCann identified himself as calling from "EMD Serono." Generally, he identified himself as calling from the doctor's office

when performing benefit verifications. He also stated that the prescription he received from the doctor's office came with an order form which included an authorization for Serono to perform Reimbursement Support Services.

279. McCann strongly believes that benefit verification services saved Prescribers time and money because the Drug Companies assumed the reimbursement support responsibilities, which allowed office staff and nurses to focus only on patient care.

280. McCann also performed prior authorizations for Rebif. McCann estimated that prior authorizations take 30 to 40 minutes. He typically became aware that the patient requires a prior authorization while performing a benefit verification for that patient. To that end, McCann would then talk to the prior authorization department and sometimes request that the doctor's office send him or the prior authorization unit clinical information. If the clinical information went to him, Mr. McCann would then forward it to the prior authorization unit. The prior authorization unit would then give him an answer and he would not write a report but rather call the provider to let them know the outcome.

281. McCann strongly believes that the prior authorization services saved Prescribers time and money because the MS LifeLines representatives working for the Drug Company performed all the reimbursement services and necessary follow-up to get a patient covered for Rebif.

282. McCann also performed coverage appeals. He estimates appeals took up to 30 days to complete.

283. McCann emphasized that the Drug Companies saw a positive net impact in terms of new prescriptions and refills for Rebif because of Reimbursement Support Services they provided free of charge to Prescribers. He explained that these services provided a positive impact

because the Reimbursement Support Services build brand loyalty. When the doctor is constantly writing different prescriptions for different MS products, the doctor prefers to prescribe a drug that offers a dedicated service team to work with insurance companies to obtain coverage for that specific product over products which do not offer similar services. He estimates that "thousands" of doctors write prescriptions for drugs specifically offering reimbursement support services because it is a highly valuable service to doctors. McCann's point of view is consistent with that of Relator Harris – the Reimbursement Support Services positively differentiated Rebif from its closest competitors.

284. Overall, McCann is confident that Reimbursement Support Services helped the Drug Companies distinguish and promote Rebif. He confirmed that sales reps, like Relator Harris, can go into doctors' offices and promote the Reimbursement Support Services, including benefit verification, prior authorizations and appealing denials of coverage. McCann believes, based on his experience, a medical provider will increase prescriptions of a company's drug after reimbursement services are provided. Because of this, Reimbursement Support Services are a great investment for pharmaceutical companies in general. Pharmaceutical companies that do not offer reimbursement support services are at a competitive disadvantage because these services are offered free of charge by other pharmaceutical companies, such as Serono and Pfizer.

285. McCann estimates that it would cost a provider approximately $45,000 to $52,000 per year in order to staff a person in-house to perform these same Reimbursement Support Services which Rebif's MS LifeLines personnel performed.

286. Nurse Educator Wopperer described her experience with the Reimbursement Support Services Scheme. She confirmed that once a physician prescribes Rebif, the physician's office faxes enrollment paperwork to Serono's MS LifeLines support services. Wopperer informed

that Serono offers a 24-hour nurse line as part of MS LifeLines.

287. Once the paperwork is received by MS LifeLines staff, they begin the process for enrolling the patient on Rebif. Wopperer confirmed that Serono offers prior authorizations, benefit verifications and patient assistance and she emphasized these Reimbursement Support Services to Prescribers and staff during her initial office visits when calling on and promoting to Prescribers. She stated:

> I simply go into the office and ask if somebody in the doctor's office performs prior authorizations. I then let them know that Serono has reimbursement specialists to perform that function. **Doing prior authorizations is very time-consuming and doing the paperwork for the office frees up their staff to do other things.**
> (emphasis added)

288. Wopperer informed that Serono assists physicians' offices with the insurance process as the drug costs approximately $60,000 per year. She also explained that Rebif has deductibles and co-pays so the financial assistance to patients is also a benefit. Wopperer believes Rebif's Reimbursement Support Services offer a competitive advantage because it provides an extensive service to Prescribers' offices.

289. Wopperer believes that Rebif's Nurse Educator and Reimbursement Support Services were the most comprehensive for any drug in the MS disease state.

290. Relators' investigation has confirmed that Reimbursement Support Services provide substantial value to Prescribers because they allowed Prescribers to essentially outsource, for free, the administrative tasks involved with starting and keeping a patient on Rebif; thereby, relieving the Prescribers and their staff from this administrative burden. The appeal of handling all administrative tasks associated with starting and keeping a patient on Rebif incentivized Prescribers to prescribe Rebif over competitor MS drugs.

291. Nurse Educator Van Asdian highlighted the appeal and substantial value that the

Reimbursement Support Services provided to Prescribers:

> **I think most of the physicians used the reimbursement support services because we really stressed that. That that would be less work for their office staff**. So, if they had a new patient that was starting on Rebif, all they had to do is call in, and the people back in Massachusetts where the [Serono] headquarters was, the main call center, they would call the insurance companies and **really do all of the leg work for them**. And they'd get them approved. That was with all physicians.
> (emphasis added).

292. Van Asdian emphasized that "all" of the physicians and nurses she worked with utilized the Reimbursement Support Services because they were "excellent."

293. Relators' investigation has confirmed that the Reimbursement Support Services also provided independent value to Prescribers because they served to significantly reduce or, in some instances, eliminate the administrative costs and burden associated with prescribing Rebif which Prescribers would have otherwise necessarily incurred when prescribing another MS drug. But-for Defendants undertaking all administrative tasks associated with prescribing Rebif, Prescribers and their staff would have had to either perform these tasks themselves or outsource these tasks to third-party vendors for a fee.

294. The independent value the Reimbursement Support Services provided to Prescribers is further highlighted by that fact that, regardless of which MS drug a Prescriber prescribes, the Prescriber must perform these administrative tasks as an inherent part of the Prescriber's duty of care. As such, the fact that the Drug Companies provided these Support Services complementary with Rebif while other drug companies selling competitor MS drugs did not evidences the substantial independent value these support services provided to Prescribers.

295. Put simply, in exchange for prescribing Rebif, Defendants would assume the Prescriber's administrative responsibilities and costs associated with starting a patient on Rebif.

The more a Prescriber prescribed Rebif as a percentage of its overall prescription volume, the greater the savings and profits to the practice, as time and money spent on handling Support Services for Rebif would now fall exclusively on Defendants. These Support Services were the "carrot" or remuneration dangled to induce Prescribers to prescribe Rebif to their MS patients. Prescribers could earn more if they prescribed Rebif.

296. Rather than promoting and marketing its drugs based on patient outcomes and efficacy, Serono and Pfizer introduced an additional incentive for Prescribers to recommend its drugs to patients. Serono knew that this service would present a tangible value to the providers. When that offer was accepted, the provider received the benefits of the Support Services without actually having to pay for those services.

297. By providing a Prescriber Reimbursement Support Services, the Drug Companies gave Prescribers a tangible "in kind" benefit that greatly reduced and in some instances eliminated a Prescriber's administrative costs related to prescribing Rebif and thus induced Prescribers to choose Rebif over a competitor's MS drug.

298. Most importantly, these Reimbursement Support Services resulted in greater profits for Prescribers prescribing Rebif because they "eliminate[d] an expense that [the provider] would have otherwise incurred."[57] Such "in kind" remuneration given, in part, to induce a recommendation and prescription for Rebif constitutes an unlawful kickback under the AKS.

299. In addition to the above, the Defendants would have detailed electronic records peculiarly in its control which would easily identify additional details about each Prescriber for whom it performed a benefit verification, prior authorization and/or coverage appeal. The records were created by the Defendants and are maintained in the ordinary course of its business. The

[57] Compliance Program Guidance for Pharmaceutical Manufacturers, 68 F.R. 23, 731 Section II (2) (May 5, 2003)("CPG").

records would show each instance a Reimbursement Support Service was performed for a Prescriber, including the name of the employee performing the task, the dates and times the task(s) was performed, the name of the patient's insurance and the outcome of the tasks performed.

300. In sum, Reimbursement Support Services provide substantial independent value to Prescribers because these Support Services reduce, and in some instances, eliminate the administrative costs associated with prescribing drugs and, therefore, increase profitability for physicians and practices.

301. By providing these Reimbursement Support Services to Prescribers in tandem with a Rebif prescription, the Defendants induced Prescribers to prescribe Rebif over other MS drugs and engaged in an unlawful remuneration scheme in violation of the AKS.

The Individuals Involved in the Reimbursement Support Services Scheme

302. The Reimbursement Support Services scheme was designed and approved as part of a collaboration between Serono and Pfizer. These "Support Services" were administered by Serono pursuant to its agreement with Pfizer. Serono created and maintained a manual that provided and explained the operations and procedures for the Support Services, which was also approved by Pfizer. Serono also recruited and employed the personnel who provide Support Services and interact with patients who had been prescribed Rebif, as well as the employees who manage and coordinate the administration of the Support Services. Together, Serono and Pfizer monitor and oversee the administration of the Reimbursement Support Services.

303. As with the Free Nurse Educator scheme and the White Coat Marketing scheme developed and implemented by Serono, Pfizer, Quintiles and RXC detailed above, numerous individuals, in addition to the previously listed corporate actors, were involved in the design, approval and implementation of the Reimbursement Support Services scheme including but not

limited to:

Name	Employer	Title/Dates of Employment	Role
Fernando Dangond	Serono	Senior Medical Director, Neurology: 03/2008 – 01/2012 Head, Neurodegenerative Diseases: 2012 – 2015 Senior Medical Director: 2015 – 2017 Neurology and Executive Medical Director: 01/2018 – present	Helped design, develop and operate the Reimbursement Support Services. Involved in launching Rebif product and medical representation in due diligence.
Frank Dangora	Serono	Territory Manager, Reimbursement: 02/2004 – 10/2013	Managed Rebif Reimbursement Support Services to patients, nurses and physicians to increase Rebif demand/sales with focus on copay assistance for Medicare D plans.
Helen Gray	Serono	Director of Patient Value, Global Business Franchise Neurology & Immunology: 01/2013 – 04/2015 Director of Strategic Marketing: 04/2015 – 01/2017 Medical Director: 01/2017 – present	Assisted in directing and operating Rebif Reimbursement Support Services to patients, prescribers and payors.
Jack Wilson	Serono/Pfizer	Serono - Vice President, Marketing: 2015 – 2017 Pfizer – Senior Manager, Neuroscience: 2004-2007	Advertised Rebif Reimbursement Support Services for Serono employees. Coordinated launch and co-promotion of Rebif between Serono and Pfizer.
Jim Guardino	Serono	Strategic Account Manager: 10/2008 – 10/2012 Thought Leader Liasion: 10/2012 – 11/2014 Sales Training Manager: 11/2014 – 12/2015 Associate Director, US Neurology & Immunology Field Force Effectiveness: 12/2015 – present	Managed and administered the Rebif Reimbursement Support Services.

Name	Employer	Title/Dates of Employment	Role
Michael Calabro	Serono	Thought Leader Liaison: 10/2010 – present	Coordinated Rebif field representatives, including Nurse Educators and Reimbursement Support Service Specialists in New Jersey, Pennsylvania, Delaware and Ohio.
Michael Lucy	Serono	Regional Account Manager: 02/2010 – 11/2014 Northeast US Area Business Director, Neurology & Immunology: 11/2014 – present	Oversaw coordination of various Rebif Nurse Educators and Reimbursement Support Services.
Scott Holiday	Serono	Area Business Director, Neurology: 06/2015 – present	Led and managed coordination of Field Nurse Educators and Reimbursement Support Services to increase Rebif sales.
Christie Spencer	RXC	Vice President: 09/2008 – 01/2011	Partnered with pharmaceutical companies to develop marketing strategies and implement these strategies by deploying Reimbursement Support Services.
Danielle Pope	RXC	Case Manager: 01/2016 – 07/2016	Assisted patients transitioning to Rebif obtain coverage for medication by performing provider Reimbursement Support Services in the form of benefit investigations.
Emily Murphy	RXC	Case Manager: 08/2005 – 05/2010 Subject Matter Expert: 05/2010 – 06/2013 Program Supervisor: 06/2013 – 04/2014 Associate Program Manager: 04/2014 – 03/2015 Program Manager: 03/2015 – present	Oversaw, managed and approved Rebif Reimbursement Support Services to conform to contracts with pharmaceutical companies.
Grant Compton	RXC	Director, Specialty brand Support Operations: 2014 – present	Manage and oversee client service programs, including Reimbursement Support Services and Nurse Educators Program.

Name	Employer	Title/Dates of Employment	Role
Howard Luo	RXC	Case Manager: 08/2017 – present	Provides Reimbursement Support Services by ensuring patients qualify for Rebif with insurance.
Steve Lynch	RXC	Vice President of Business Development: 01/2016 - present	Organizes with Serono/Pfizer to create and develop Rebif marketing strategies including through Field Nurse Educators Program and Reimbursement Support Services.

304. The Reimbursement Support Services program was largely delivered by RXC and Quintiles nurses that administered Serono's Free Nurse Educators program.

305. These and the other above-mentioned individuals played significant roles in designing, developing and implementing the Reimbursement Support Services scheme with the singular goals of increasing Rebif prescriptions and sales.

The Duration of the Reimbursement Support Services Scheme

306. As with the Nurse Educator and White Coat Marketing programs, Relator's investigation establishes that the Reimbursement Support Services programs were viewed by Serono and Pfizer as a key part of its efforts to promote and drive Rebif prescriptions and sales and, accordingly, have been administered continuously once established for Rebif.

307. For instance, Fernando Dangond (Dangond) worked for Serono in various roles as outlined above, but most recently as Head of Neurodegenerative Disease from 2012 through 2015 and Senior Medical Director and Head from 2015 through 2017 in Massachusetts. During that time-frame, Dangond launched Rebif product support services including representing Prescribers in due diligence procedures through Reimbursement Support Services.

308. Additionally, Frank Dangora (Dangora) worked for Serono as a Territory Manager

for Reimbursement from February 2004 through October 2013. In that role, Dangora managed Rebif Reimbursement Support Services to patients, nurses and physicians throughout the Pennsylvania and New Jersey region. Dangora focused especially on Reimbursement Support Services with Medicare Part D plans copay assistance.

309. Further, Christie Spencer (Spencer) worked for RXC as Vice President from September 2008 through January 2011. Spencer partnered with Serono and Pfizer to develop marketing strategies and implement these strategies by deploying Reimbursement Support Services.

310. Relator Harris identified Georgia based Prescribers who were targeted with and received the free Reimbursement Support Services in the manner set forth herein. Those Prescribers are as follows: Dr. Mitzi Williams; Dr. Jeffrey English; and Dr. Robert Gilbert from the MS Center in Atlanta; Dr. Ben Thrower, Dr. Cheryl Lorring and Dr. Guy Buckle of the Sheppard Center; and Dr. Reinaldo Verson of the Columbus MS Center.

311. Relators' investigation identified Utah based Prescribers who were targeted with and received the free Reimbursement Support Services in the manner set forth herein. Those Prescribers are as follows: Dr. Jeffrey Groves; Nurse Practitioner Julia Klein; Dr. Denise Skuster; Dr. John Rose; and, Dr. Joseph Watkins.

312. Relators' investigation identified several New York based Prescribers who were targeted with and received the free Reimbursement Support Services in the manner set forth herein. Those Prescribers are as follows: Nurse Practitioner Jeanne Ceballos; Dr. Keith Edwards; Dr. Burk Jubelt; Nurse Practitioner Pamela Kirch; and, Dr. Hassan Shukri-Mahmod.

313. Relators' investigation identified several New Jersey and Pennsylvania based Prescribers who were targeted with and received the free Reimbursement Support Services in the

manner set forth herein. Those Prescribers are as follows: Dr. Syed Jaffery; Dr. Thomas Mirsen; Dr. Manzoor Abidi; Dr. Ravi Dukkipati; Dr. Thomas Leist; and, Dr. Dina Jacobs.

314. Upon information and belief set out in the previous paragraphs, the free Reimbursement Support Services scheme dates back from approximately 2004 through the present.

315. Through Relators' investigation, Relators have learned that drug companies, including Serono and Pfizer, enter into detailed contracts with vendors such as the co-Defendant vendors. These contracts are re-negotiated based upon the drug companies' "ROI" or return on investment of drug sales from the payments it makes to the co-Defendant vendors. Those contracts include an attached Scopes of Work, referred to as "SOWs." The SOW for Serono and Pfizer's contract spells out in detail each discrete task that is to be performed and the payment that will be made for each. These contracts are not publicly available but are in the exclusive possession and control of the defendants and will spell out the precise dates that the scheme began.

The Geographic Span of the Reimbursement Support Services Scheme

316. The Reimbursement Support Services program is administered nationwide and is available to patients throughout the United States.

317. Relator's investigation reveals that the Reimbursement Support Services program has been implemented in every region of the United States and in almost all 50 states.

DEFENDANTS' FRAUDULENT SCHEMES RESULTED IN THE SUBMISSION OF FALSE CLAIMS TO GOVERNMENT HEALTHCARE PROGRAMS

318. During the relevant time period, Defendants' actions knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Federal Healthcare Programs for Rebif provided to beneficiaries as a result of

Defendants' illegal marketing and quid pro quo arrangements. Those false claims have caused the Government to disburse billions of dollars in reimbursements that were tainted by kickbacks and should not have been paid. This conclusion is compelled by numerous facts, as detailed below.

Specific Examples of False Claims Resulting from Prescribers Targeted with the White Coat Marketing Scheme, the Free Nurse Scheme, and the Reimbursement Support Services Scheme

319. Relator's investigation has identified specific Prescribers who were targeted with the White Coat Marketing Scheme, the Free Nurse Kickback Scheme, and the Reimbursement Support Services Scheme and provides examples of claims resulting from these Prescribers.

320. Attached as Exhibit A are some examples of specific claims submitted for Rebif by the Prescribers mentioned in this complaint who were targeted with the White Coat Marketing Scheme and received remuneration from the Free Nurse Services and the Free Reimbursement Support Services Schemes. Each row represents a specific claim submitted for reimbursement to Medicare.

321. Attached as Exhibit B are the aggregate annual Rebif Medicare claims submitted by the Prescribers mentioned in this complaint who were targeted with the White Coat Marketing Scheme and received remuneration from the Free Nurse Services and the Free Reimbursement Support Services Schemes.

322. Attached as Exhibit C are some of the Rebif New Jersey Medicaid claims resulting from some of the Prescribers mentioned in this complaint who were targeted with the White Coat Marketing Scheme and received remuneration from the Free Nurse Services and the Free Reimbursement Support Services Schemes.

323. Each of the claims identified in Exhibits A through C are linked to the Defendants' unlawful conduct detailed above, which gives rise to the false claims at issue herein.

324. These specific claims are linked to the Defendants' conduct alleged herein because each claim resulted from a prescription written by a Prescriber who was offered and/or received unlawful remuneration under the Free Nurse Kickback Scheme. This unlawful remuneration saved the Prescribers and their staff time, resources, and money that the Prescriber would otherwise have had to incur to provide follow-up care and monitoring for patients treating with Rebif.

325. These specific claims are further linked to the Defendants' conduct alleged herein because each claim resulted from a prescription written by a Prescriber who was offered and/or received unlawful remuneration under the Reimbursement Support Services Scheme. This unlawful remuneration saved the Prescribers and their staff time, resources, and money that the Prescriber would otherwise have had to incur to perform administrative tasks necessary for the patients to receive treatment with Rebif.

326. These specific claims are further linked to the Defendants' conduct alleged herein because each claim resulted from a prescription written by a Prescriber who also was targeted by Serono's White Coat Marketing Scheme, which involved Serono and Pfizer paying compensation to Quintiles and RXC nurses to recommend Rebif.

Defendants Specifically Targeted Government Healthcare Programs

327. Relator's investigation indicates that the vast majority of patients for whom Rebif was prescribed by Prescribers targeted w Defendants are recipients of Medicare, Medicaid, TRICARE, or Medicare supplement healthcare insurance programs.

328. Indeed, many of these same Prescribers are among the Top Medicare Prescribers of Rebif nationally.[58]

Given the Breadth of Defendants' Misconduct and the Large Volume of Claims

[58] ProPublica, *Prescriber Checkup, available at* https://projects.propublica.org/checkup/drugs/1761?sort=drug_claims (last accessed Nov. 13, 2018).

Submitted to Government Healthcare Programs, It Is Statistically Impossible that Defendants' Conduct Did Not Result in the Submission of False Claims

329. Defendants employed the three schemes detailed above across the nation, and Rebif was marketed, prescribed, and sold nationwide. Claims were submitted to federal and state healthcare programs, including Medicare and Medicaid, in most, if not all, states. Given that the marketing schemes described herein were actively promoted by Defendants and widely used by Prescribers, it is statistically impossible that claims for Rebif were not submitted to Government programs.

330. Approximate Medicare claims data concerning Rebif for certain years is summarized below.

Claims Related to Rebif

331. There is an abundance of evidence supporting a reliable indicia that other claims were submitted to Government payers.

332. For example, in 2015, approximately 47,000 Medicare Part D Claims were submitted for Rebif, resulting in approximately $274 million in nationwide spending.[59] Over $10 million was spent in each of 8 states. The top 3 states in terms of spending were New York ($19.2 million), Florida ($18.4 million) and Michigan ($18 million). A further breakdown of each state's 2015 Medicare claims data is summarized in the table below. Relator's investigation confirms that the conduct identified herein took place nationwide.[60]

2015 Rebif Medicare Claims Data (approximate value)			
State	**Patients**	**Claims**	**Cost (in millions)**
Alabama	86	739	$4.39
Alaska		35	$202K

[59] ProPublica, *Prescriber Checkup, Rebif, available at* https://projects.propublica.org/checkup/drugs/1761 (last accessed Nov. 8, 2018).
[60] *See id.* Note, patient data was unavailable for Alaska, Hawaii, Rhode Island, Vermont and Wyoming.

2015 Rebif Medicare Claims Data (approximate value)			
State	**Patients**	**Claims**	**Cost (in millions)**
Arizona	79	605	$3.72
Arkansas	36	321	$1.79
California	286	2,447	$13.8
Colorado	125	1,012	$6.08
Connecticut	49	420	$2.47
Delaware	22	317	$1.18
Florida	372	3,269	$18.4
Georgia	136	1,030	$5.99
Hawaii		67	$375K
Idaho	33	355	$1.89
Illinois	263	2,334	$13.4
Indiana	169	1,630	$8.62
Iowa	55	421	$2.48
Kansas	56	620	$3.15
Kentucky	99	854	$4.83
Louisiana	55	481	$2.76
Maine	61	477	$2.79
Maryland	95	723	$4.13
Massachusetts	109	917	$5.55
Michigan	362	3,002	$18
Minnesota	158	1,438	$8.19
Mississippi	60	444	$2.7
Missouri	144	1,297	$7.5
Montana	16	141	$826K
Nebraska	25	238	$1.38
Nevada	46	446	$2.64
New Hampshire	32	304	$1.64
New Jersey	146	1,098	$7.47
New Mexico	39	330	$1.95
New York	382	3,317	$19.2
North Carolina	182	1,495	$9.33
North Dakota	23	223	$1.29
Ohio	255	2,185	$12.3
Oklahoma	48	390	$2.34
Oregon	57	409	$2.53
Pennsylvania	305	2,794	$15.1
Rhode Island		102	$566K
South Carolina	95	802	$4.7
South Dakota	28	261	$1.61
Tennessee	138	1,173	$7.23
Texas	244	2,052	$12.5

2015 Rebif Medicare Claims Data (approximate value)			
State	**Patients**	**Claims**	**Cost (in millions)**
Utah	44	364	$2.15
Vermont		69	$339K
Virginia	99	861	$4.73
Washington	146	1,199	$7.28
West Virginia	45	380	$2.18
Wisconsin	126	1,033	$5.93
Wyoming		55	$313K
Total	5,339	47,300	$274

333. Moreover, in 2015, Medicaid's total reimbursement per prescription was $5,200 and the gross cost to Medicaid for all Rebif prescriptions totaled $131.28 million.[61]

DEFENDANTS ACTED WITH SCIENTER WHEN IMPLEMENTING AND PROFITING FROM THE THREE FRAUDULENT SCHEMES

334. As significant players in the healthcare marketplace, Defendants are acutely aware of the need to comply with the AKS in promoting their drugs to health care professionals.

335. Indeed, in light of significant settlements of False Claims Act litigations brought against various pharmaceutical companies, Serono entered into corporate integrity agreements that require it to commit to the highest level of ethical conduct, which includes complying with all applicable laws and regulations concerning the sale and marketing of healthcare products, including the AKS.

336. Serono's corporate integrity statement makes clear that:

> EMD SERONO IS DEDICATED TO DELIVERING INNOVATIVE PRODUCTS THAT FIGHT DEBILITATING DISEASES AND IMPROVE THE LIVES OF PATIENTS. OUR COMMITMENT TO INTEGRITY IN EVERYTHING WE DO IS

[61] Center for Evidence-Based Policy, *State Medicaid Alternative reimbursement and Purchasing test for High-cost Drugs (SMART-D)* (September 2016), *available at* http://smart-d.org/wp-content/uploads/2016/09/SMART-D-Summary-Report-Final.pdf (last accessed, Nov. 8, 2018).

> FUNDAMENTAL TO ACHIEVING THIS VISION. To achieve our objectives, we will apply the highest legal and ethical standards to all of our business activities. EMD Serono will comply with all applicable laws and expects all employees to do the same. No employee may violate the law on EMD Serono's behalf, or direct anyone else to do so. Even more basically, EMD Serono expects employees to perform their jobs with honesty and integrity. It is our pledge to always do what is right.[62]

337. To further its supposed commitment to integrity, Serono adopted a specific AKS policy aimed at ensuring Serono's compliance with the False Claims Act and the AKS.

338. Serono's AKS policy expressly prohibits Serono's employees from providing "improper inducements to prescribe or purchase EMD Serono products, regardless of whether a federal healthcare program is involved." Specifically, Serono's AKS policy states:

> **The anti-kickback law makes it a crime to pay or receive anything of value to induce the prescribing or purchasing of items or services paid for by a federal healthcare program**. As applied to pharmaceutical companies, the law prohibits payments intended to induce someone to purchase or prescribe a drug reimbursable under a federal healthcare program or to reward someone for purchasing or prescribing a drug. Put simply, do not "buy business." Under the anti-kickback law, questions about underlying intent might be raised concerning almost any type of payment, including direct compensation, educational and research grants, speaker fees, and reimbursement for participation in clinical trials.
>
> A principal purpose of the anti-kickback law is to protect the independence and objectivity of decisions affecting federal healthcare programs and their patients. A physician's treatment decision should be free from considerations of personal gain.
>
> Many states have laws similar to the federal anti-kickback statute making it a violation to pay anything of value to influence prescriptions paid for by state healthcare programs, private health plans and even individuals. Accordingly, **EMD Serono prohibits improper inducements to prescribe or purchase EMD Serono products, regardless of whether a federal healthcare program is**

[62] *See* EDM Serono, *Code of Conduct*, *available at* https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/code-of-conduct.pdf (last accessed Nov. 7, 2018).

> **involved**.[63]
> (emphasis added).

339. To that end, Serono's AKS policy provides that:

> **Only items designed primarily for the education of patients or healthcare professionals that are less than $100 in value and do not have value to the healthcare professionals outside of their professional responsibilities may, on an occasional basis, be offered to healthcare professionals**. No other materials, including materials for the personal benefit of healthcare professionals, can be offered.[64]
> (emphasis added).

340. Serono's AKS policy makes it clear that offering any item or service that provides healthcare providers with substantial value (greater than $100) and that value is independent of the item or service being offered constitutes illegal remuneration expressly prohibited by the AKS.

341. Moreover, both Serono and Pfizer are members of the Pharmaceutical Research and Manufacturers of America ("PhRMA").[65] The PhRMA is an organization that represents the country's leading biopharmaceutical researchers and biotechnology companies. The PhRMA promulgates the PhRMA Code as "part of an ongoing effort to ensure that biopharmaceutical marketing practices and informational activities comply with the highest ethical and professional standards."[66]

342. Serono and Pfizer are not only members of the PhRMA but also signatories to the PhRMA Code and have, thereby, announced their intention to abide by the Code.[67] For example, Serono's Code of Conduct mandates all Serono employees to abide by the PhRMA Code:

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[63] *See id.*
[64] *See id.*
[65] *See* PhRMA Code on Interactions with Healthcare Professionals, *Signatory Companies*, *available at* http://phrma-docs.phrma.org/files/dmfile/Signatory-Companies-May-2018.pdf (last accessed Nov. 7, 2018).
[66] PhRMA, *Press Release: PhRMA Code on Interactions with Healthcare Professionals* (Apr. 30, 2013), *available at* http://www.phrma.org/press-release/phrma-code-on-interactionswith-healthcare-professionals-reaches-new-milestone-with-54th-signatory-company (last accessed Nov. 7, 2018).
[67] *See*, *supra*, note 65.

> **To maintain the integrity of our relationships with providers and to help EMD Serono employees abide by the anti-kickback law, EMD Serono has adopted the PhRMA Code on Interactions with Healthcare Professionals**, a set of industry guidelines governing relationships between pharmaceutical firms and physicians. EMD Serono employees should follow the PhRMA Code as if it were an internal company policy.[68]

343. The PhRMA Code prohibits pharmaceutical companies, like Serono and Pfizer, from providing or offering grants, subsidies, support, or practice-related items "to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products." In fact, the PhRMA Code specifically states that "[**n]othing** should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices."[69] The PhRMA Code further mandates pharmaceutical companies to train all representatives acting on behalf of the pharmaceutical company to ensure that they comply with the applicable laws, regulations and industry codes when marketing to healthcare professionals.[70]

344. The express language of Serono's AKS policy which references its adoption of the PhRMA Code evidences Serono's awareness and understanding of the AKS's prohibition on illegal remuneration arrangements. By virtue of adopting an AKS policy, Serono essentially

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[68] *See* EDM Serono, *Code of Conduct*, *available at* https://www.emdserono.com/content/dam/web/corporate/non-images/country-specifics/us/code-of-conduct.pdf (last accessed Nov. 7, 2018).

[69] PhRMA, Code on Interactions with Healthcare Professionals, at 13 (July 2008), *available at* http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008- 1.pdf (last accessed, Nov. 8, 2018) (emphasis added) (stating "[n]o grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.)

[70] *Id.* at 14 (emphasizing that "[c]ompanies should ensure that all representatives who are employed by or acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations and industry codes of practice, including this Code, that govern the representatives' interactions with healthcare professionals….Companies should provide updated or additional training in all of these areas as needed for their representatives who visit healthcare professionals. Companies should also assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct. Companies should take appropriate action when representatives fail to comply.").

publicly announced that it fully knew that the schemes involving the Nurse Educator, White Coat Marketing and Reimbursement Support Service Programs were prohibited by the AKS because they served to induce Prescribers to prescribe the Serono drug Rebif and it did so knowing that these claims would be submitted to and paid for by Government Healthcare Programs.

345. Despite Serono's adoption of an AKS policy and the PhRMA Code, Serono engaged in prohibited practices by implementing the Nurse Educator, White Coat Marketing and Reimbursement Support Service Programs which provided substantial independent value to Prescribers in exchange for prescribing Rebif to their patients.

346. Serono was completely aware of the AKS and its prohibitions; yet, it knowingly and intentionally violated the AKS by developing and implementing a sophisticated scheme of programs aimed at inducing Prescribers to prescribe Rebif and defraud the Government.

347. Although Serono and its co-Defendants knew that the AKS prohibited them from providing anything of value to providers or from giving kickbacks to promote Rebif, Defendants disregarded the law, choosing instead to put sales growth and profits before their duties to comply with the law and ensure patient safety and integrity in the healthcare marketplace.

348. Together, the Defendants designed, developed and implemented the three fraudulent schemes with the specific knowledge and intent of inducing Prescribers to recommend and prescribe Rebif, and ultimately causing pharmacies to submit thousands of claims tainted by illegal kickbacks to federal Government healthcare programs seeking reimbursement. In doing so, Defendants knowingly and intentionally violated the FCA and the AKS.

DEFENDANTS' ACTIONS ARE NOT SUBJECT TO ANY SAFE HARBOR

349. Although the AKS provides certain safe harbors that immunize conduct that may otherwise be illegal, none apply here.

350. The only safe harbor that Defendants could conceivably invoke, the so-called "personal services" safe harbor, 42 C.F.R. § 1001.952(d), does not apply for at least the following distinct reasons.

351. First, the "personal services" safe harbor does not apply unless the contracts at issue "cover[] all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent." The contracts between the Drug Companies and the Consultants fall short of spelling all of the services the Quintiles/RXC nurses have performed for Serono and Pfizer. In particular, the contracts do not recite or even suggest the fact that the nurses would act as white-coat marketers for Serono/Pfizer's drug, or effectively supplant Prescribers' staff.

352. Second, the "personal services" safe harbor expressly covers only services that "do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law." In other words, conduct that expressly violates the AKS – such as paying direct remuneration to Prescribers – is not immunized by using an intermediary to recommend products. Indeed, guidance issued by the HHS when adopting the safe harbor provisions makes clear that the "personal services" safe harbor does not exempt payments to "health care provider[]" intermediaries who, based on their "position of public trust," thereafter recommend that other health care professionals or patients purchase the products or services of the company from whom they received payment.[71]

353. None of the AKS safe harbors apply and Defendants remain fully liable under the

[71] *See* 56 Fed. Reg. 35952, at *35974 (1991) ("[W]e have experienced many instances where promoters and consultants have become involved in marketing activities that encourage health care providers and others to violate the statute . . . . It would be inappropriate to allow such activities to receive safe harbor protection. Thus, we are adding paragraph (d)(6) to this safe harbor provision to make clear that the service that is contracted for is not protected if it involves the counselling or promotion of a business arrangement or other activity which itself constitutes a violation of any State or Federal law.")

AKS.

DAMAGES

354. While the Drug Companies and the Consultants profited from the illegal schemes described in this Complaint, the federal Government Healthcare Programs were made to bear the costs. From or around 2006 to the present, Defendants' purposeful and illegal marketing and *quid pro quo* arrangements have caused Prescribers, pharmacies, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to the federal Government Healthcare Programs for the Drug Companies' drug.

355. These claims were induced by illegal and fraudulent schemes and, thus, constitute false claims. Consequently, the federal Government Healthcare Programs have disbursed millions of dollars in reimbursements for a drug whose prescriptions were tainted by these illegal and fraudulent kickbacks that should not have been paid.

SUMMARY

356. The three unlawful schemes described herein were deliberately planned by Serono and Pfizer's leadership and represent an integral part of Serono and Pfizer's marketing strategy for Rebif.

357. Thus, all the specifics of Defendants' unlawful schemes – the "what, how, who, where, and when" of Defendants' misconduct – are well known to Defendants.

358. The Defendants are liable to the federal Government for damages based on the payment of all claims submitted to Federal Healthcare Programs for prescriptions written for the Drug Companies' covered drugs beginning from the time they began paying remuneration as detailed above up and through the present because the claims were the result of recommendations induced, in whole or in part, by remuneration.

359. Compliance with the AKS is a precondition of payment by virtue of federal and state statutes, regulations, provider agreements and contracts.

360. The certifications and attestations signed by physicians, pharmacies, PBMs and Part D sponsors certified compliance with the AKS. The kickbacks that were paid to and received by the Consultants and other health care professionals as detailed above to recommend the Drug Companies' drugs as alleged herein rendered those certifications and attestations false. Those false statements were material to the false claims submitted for the covered drugs.

361. Claims for the Drug Companies' drugs arising from the kickbacks expressly and impliedly misrepresented compliance with a material condition of payment—compliance with the AKS. Claims that include items or services resulting from a violation of the AKS constitute false or fraudulent claims under the AKS.[72]

362. By providing remuneration to the Consultants and other health care professionals, the Drug Companies intended to induce those parties to recommend and/or prescribe the Drug Companies' drugs.

363. It was reasonably foreseeable that some of those prescriptions would be for Federal Healthcare Programs' beneficiaries and that claims for those prescriptions would be submitted to Federal Healthcare Programs. In fact, thousands of such prescriptions or claims based on such prescriptions were submitted to and paid for by Federal Healthcare Programs.

[72] *See* 42 U.S.C. § 1320a-7b(b).

COUNTS

FIRST COUNT
FALSE CLAIMS ACT
UNITED STATES CODE 31 U.S.C. §§ 3729-3733 *et. seq.*

364. Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.

365. Relators bring these claims on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733, against Defendants, for knowingly causing to be presented false claims to the Federal Healthcare Programs. From on or about 2006 through the present, in this District and elsewhere throughout the United States, Defendants knowingly and willfully have violated the FCA by causing false claims tainted by illegal kickbacks to be submitted to the Federal Healthcare Programs.

366. As a result of the Drug Companies' kickbacks paid to the Consultants and other health care professionals to recommend the Drug Companies' drugs in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(2), false and fraudulent claims for payment based on these prescriptions were made to federal health care programs.

367. Accordingly, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(l) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

368. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

369. Relators also bring this action under the False Claims Act, 31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

370. As a result of the Drug Companies' kickbacks paid in violation of the federal AKS, 42 U.S.C. § 1320a-7b(h)(2), Defendants knowingly caused pharmacies, Part D sponsors, fiscal intermediaries and others to make false records or statements that were material to false or fraudulent claims for payment submitted to the Federal Healthcare Programs. Those false records or statements by physicians in turn caused the certifications and attestations signed by pharmacies, PBMs and Part D sponsors that certified compliance with the AKS to be false.

371. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

SECOND COUNT
CALIFORNIA FALSE CLAIMS ACT
CAL. GOV'T CODE §§ 12650 – 12655

372. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12655.

373. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

374. Defendants violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

375. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

376. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

377. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

THIRD COUNT
COLORADO MEDICAID FALSE CLAIMS ACT
COL. REV. STAT. §§ 25.5-4-303.5 – 25.5-4-309

378. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 – 25.5-4-309.

379. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

380. Defendants violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

381. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

382. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

383. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

FOURTH COUNT
CONNECTICUT FALSE CLAIMS ACT FOR MEDICAL ASSISTANCE PROGRAMS
CONN. GEN. STAT. ANN. §§ 17B-301 *ET SEQ.*

384. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. Ann. §§ 17b-301 *et seq*.

385. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

386. Defendants violated the Connecticut False Claims Act for Medical Assistance Programs by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

387. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

388. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

389. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

FIFTH COUNT
DELAWARE FALSE CLAIMS AND REPORTING ACT
6 DEL C §§ 1201(A)(1) AND (2)

390. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, 6 Del C §§ 1201(a)(1) and (2).

391. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

392. Defendants violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

393. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

394. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

395. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

SIXTH COUNT
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT
D.C. CODE ANN. §§ 2-308.13 – 308.1526[73]

396. This is a claim for treble damages and civil penalties under District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 2-308.13 – 308.1526.

397. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

398. Defendants violated the District of Columbia Procurement Reform Amendment Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

399. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

400. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

[73] Repealed effective April 8, 2011, and re-codified as D.C. Code Ann. § 2-381.01 *et seq*. without *qui tam* provisions.

401. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

SEVENTH COUNT
FLORIDA FALSE CLAIMS ACT
FLA. STAT. §§ 68.081 – 68.090

402. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. §§ 68.081 – 68.090.

403. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

404. Defendants violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

405. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

406. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

407. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

EIGHTH COUNT
GEORGIA STATE FALSE MEDICAID CLAIMS ACT
GA. CODE §§ 49-4-168 *ET SEQ.*

408. This is a claim for treble damages and civil penalties under Georgia State False Medicaid Claims Act, Ga. Code §§ 49-4-168 *et seq*.

409. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

410. Defendant violated the Georgia State False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

411. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

412. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

413. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

NINTH COUNT
HAWAII FALSE CLAIMS ACTS
HAW. REV. STAT. §§ 661-21 – 661-29

414. This is a claim for treble damages and civil penalties under the Hawaii False Claims Acts, Haw. Rev. Stat. §§ 661-21 – 661-29.

415. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

416. Defendants violated the Hawaii False Claims Acts by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

417. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

418. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

419. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

TENTH COUNT
ILLINOIS FALSE CLAIMS ACT
740 ILL. COMP. STAT. 175/1 *ET SEQ.*

420. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq*.

421. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

422. Defendants violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

423. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

424. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

425. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

ELEVENTH COUNT
INDIANA FALSE CLAIMS AND WHISTLEBLOWERS PROTECTION ACT
IND. CODE ANN. §§ 5-11-5.5-1 – 5-11-5.5-18

426. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18.

427. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

428. Defendants violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

429. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

430. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

431. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

TWELFTH COUNT
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
LA. REV. STAT. §§ 46:437 *ET SEQ.*

432. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437 *et seq*.

433. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

434. Defendants violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

435. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

436. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

437. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

THIRTEENTH COUNT
MARYLAND FALSE HEALTH CLAIMS ACT OF 2010
MD. CODE ANN., HEALTH-GENERAL §§ 2-601 *ET SEQ*.

438. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-General §§ 2-601 *et seq*.

439. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

440. Defendants violated the Maryland False Health Claims Act of 2010 by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland, as described herein.

441. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

442. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

443. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

FOURTEENTH COUNT
MASSACHUSETTS FALSE CLAIMS LAW
MASS. GEN. LAWS ANN. CH. 12 §§ 5A *ET SEQ*.

444. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. Ch. 12 §§ 5A *et seq*.

445. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

446. Defendants violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

447. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

448. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

449. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

FIFTEENTH COUNT
MICHIGAN MEDICAID FALSE CLAIMS ACT
MICH. COMP. LAWS §§ 400.601 *ET SEQ*.

450. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq*.

451. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

452. Defendants violated the Michigan Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

453. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

454. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

455. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

SIXTEENTH COUNT
MINNESOTA FALSE CLAIMS ACT
MINN. STAT. §§ 15C.01 *ET SEQ*.

456. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq*.

457. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

458. Defendants violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

459. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

460. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

461. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

SEVENTEENTH COUNT
MONTANA FALSE CLAIMS ACT
MONT. CODE ANN. §§ 17-8-401 – 17-8-412

462. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-412.

463. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

464. Defendants violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

465. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

466. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

467. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

EIGHTEENTH COUNT
NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT
NEV. REV. STAT. ANN. §§ 357.010 – 357.250

468. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250.

469. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

470. Defendants violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

471. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

472. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

473. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

NINETEENTH COUNT
NEW JERSEY FALSE CLAIMS ACT
N.J. STAT. §§ 2A:32C-1 *ET SEQ*.

474. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq*.

475. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

476. Defendants violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

477. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

478. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

479. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

TWENTIETH COUNT
NEW MEXICO FRAUD AGAINST TAXPAYERS FALSE CLAIMS ACT, N.M. STAT. ANN. §§ 44-9-1 *ET SEQ*.

480. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers False Claims Act, N.M. Stat. Ann. §§ 44-9-1 *et seq*.

481. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

482. Defendants violated the New Mexico Fraud Against Taxpayers False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

483. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

484. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

485. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FIRST COUNT
NEW YORK FALSE CLAIMS ACT
N.Y. STATE FIN. LAW §§ 187 *ET SEQ*.

486. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq*.

487. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

488. Defendants violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

489. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

490. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which it would not otherwise have paid.

491. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SECOND COUNT
NEW YORK CITY FALSE CLAIMS ACT
ADMIN. CODE §§ 7-801 *ET SEQ.*

492. This is a claim for treble damages and civil penalties under the New York City False Claims Act, Admin. Code §§ 7-801 *et seq.*

493. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

494. Defendants violated the New York City False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the City of New York, as described herein.

495. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the City of New York.

496. The City of New York, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

497. By reason of these payments, the City of New York has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-THIRD COUNT
NORTH CAROLINA FALSE CLAIMS ACT
N.C. GEN. STAT. §§ 1-605 *ET SEQ.*

498. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq*.

499. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

500. Defendants violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

501. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

502. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

503. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FOURTH COUNT
OKLAHOMA MEDICAID FALSE CLAIMS ACT
OKL. STAT. TITLE 63 §§ 5053 *ET SEQ*.

504. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okl. Stat. Title 63 §§ 5053 *et seq*.

505. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

506. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

507. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

508. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

509. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FIFTH COUNT
RHODE ISLAND STATE FALSE CLAIMS ACT
R.I. GEN. LAWS §§ 9-1.1-1 *ET SEQ*.

510. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq*.

511. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

512. Defendants violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

513. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

514. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which it would not otherwise have paid.

515. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SIXTH COUNT
TENNESSEE FALSE CLAIMS ACT
TENN. CODE ANN. §§ 4-18-101 *ET SEQ*.

516. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 *et seq*.

517. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

518. Defendants violated the Tennessee False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

519. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

520. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

521. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SEVENTH COUNT
TENNESSEE MEDICAID FALSE CLAIMS ACT
TENN. CODE. ANN. §§ 71-5-181 *ET SEQ*.

522. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 *et seq*.

523. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

524. Defendants violated the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

525. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

526. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

527. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-EIGHTH COUNT
TEXAS MEDICAID FRAUD PREVENTION LAW
TEX. HUM. RES. CODE ANN. §§ 36.001 – 36.132

528. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132.

529. Relators re-allege and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

530. Defendants violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

531. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

532. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

533. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-NINTH COUNT
VIRGINIA FRAUD AGAINST TAXPAYERS ACT
VA. CODE ANN. §§ 8.01-216.1 – 216.19

534. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 216.19.

535. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

536. Defendants violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

537. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Virginia.

538. The Commonwealth of Virginia, unaware of the false or fraudulent nature of these claims, paid such claims, which it would not otherwise have paid.

539. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

THIRTIETH COUNT
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW
WIS. STAT. § 20.931

540. This is a claim for treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931.

541. Relators re-allege and incorporate the allegations in the preceding paragraphs as if set forth fully herein.

542. Defendants violated the Wisconsin False Claims for Medical Assistance Law, by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Wisconsin, as described herein.

543. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Wisconsin.

544. The State of Wisconsin, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Wisconsin would not otherwise have paid.

545. By reason of these payments, the State of Wisconsin has been damaged, and continues to be damaged, in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relators request that judgment be entered against Defendants Pfizer, Serono, Quintiles and RXC as follows:

(a) treble the United States' damages in an amount determined at trial, plus an $11,000 penalty for each false claim submitted in violation of the FCA;

(b) administrative civil penalties of $50,000 for each AKS violation, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose;

(c) an award of costs, Relators' attorneys' fees in bringing this action and the maximum Relators' award allowed pursuant to the FCA; and

(d) such further relief as is proper.

Respectfully submitted,
GeyerGorey, LLP

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DATE: December 27, 2018